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(54) **METHODS AND APPARATUS FOR
ENDOVASCULARLY REPLACING A HEART
VALVE**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

15,192 A 6/1856 Peale
2,682,057 A 6/1954 Lord

(Continued)

FOREIGN PATENT DOCUMENTS

CN 1338951 A 3/2002
DE 19532846 A1 3/1997

(Continued)

OTHER PUBLICATIONS

US 8,062,356, 11/2011, Salahieh et al. (withdrawn)
(Continued)

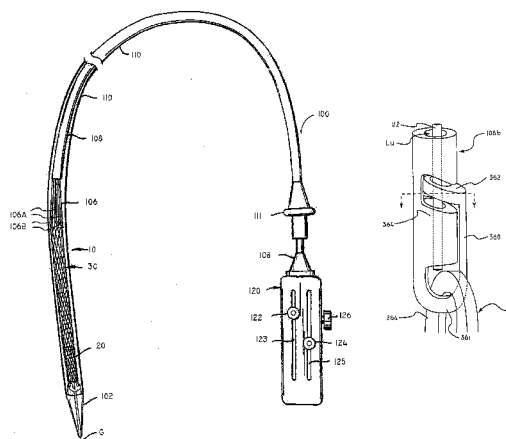
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(57) **ABSTRACT**

The invention includes methods of and apparatus for endo-vascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to change the shape of the anchor, such as by applying proximally and/or distally directed force on the anchor using a releasable deployment tool to expand and contract the anchor or parts of the anchor. Another aspect of the invention provides an apparatus including a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted to apply a non-hydraulically expanding or non-

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pneumatically expanding actuation force on the anchor to reshape the anchor.

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(56)

References Cited

U.S. PATENT DOCUMENTS

2,701,559 A 2/1955 Cooper
2,832,078 A 4/1958 Williams
3,099,016 A 7/1963 Edwards
3,113,586 A 12/1963 Edmark, Jr.
3,130,418 A 4/1964 Head et al.
3,143,742 A 8/1964 Cromie
3,334,629 A 8/1967 Cohn
3,367,364 A 2/1968 Cruz, Jr. et al.
3,409,013 A 11/1968 Berry
3,445,916 A 5/1969 Schulte
3,540,431 A 11/1970 Mobin-Uddin
3,548,417 A 12/1970 Kischer et al.
3,570,014 A 3/1971 Hancock
3,587,115 A 6/1971 Shiley
3,592,184 A 7/1971 Watkins et al.
3,628,535 A 12/1971 Ostrowsky et al.
3,642,004 A 2/1972 Osthagen et al.
3,657,744 A 4/1972 Ersek
3,671,979 A 6/1972 Mouloupoulos
3,714,671 A 2/1973 Edwards et al.
3,755,823 A 9/1973 Hancock
3,795,246 A 3/1974 Sturgeon
3,839,741 A 10/1974 Haller
3,868,956 A 3/1975 Alfidi et al.
3,874,388 A 4/1975 King et al.
3,997,923 A 12/1976 Possis
4,035,849 A 7/1977 Angell et al.
4,056,854 A 11/1977 Boretos et al.
4,106,129 A 8/1978 Carpentier et al.
4,222,126 A 9/1980 Boretos et al.
4,233,690 A 11/1980 Akins
4,265,694 A 5/1981 Boretos et al.
4,291,420 A 9/1981 Reul
4,297,749 A 11/1981 Davis et al.
4,323,358 A 4/1982 Lentz et al.
4,326,306 A 4/1982 Poler
4,339,831 A 7/1982 Johnson

4,343,048 A 8/1982 Ross et al.
4,345,340 A 8/1982 Rosen
4,373,216 A 2/1983 Klawitter
4,406,022 A 9/1983 Roy
4,423,809 A 1/1984 Mazzocco
4,425,908 A 1/1984 Simon
4,470,157 A 9/1984 Love
4,484,579 A 11/1984 Meno et al.
4,501,030 A 2/1985 Lane
4,531,943 A 7/1985 Van Tassel et al.
4,535,483 A 8/1985 Klawitter et al.
4,574,803 A 3/1986 Storz
4,580,568 A 4/1986 Gianturco
4,592,340 A 6/1986 Boyles
4,602,911 A 7/1986 Ahmadi et al.
4,605,407 A 8/1986 Black et al.
4,610,688 A 9/1986 Silvestrini et al.
4,612,011 A 9/1986 Kautzky
4,617,932 A 10/1986 Kornberg
4,643,732 A 2/1987 Pietsch et al.
4,647,283 A 3/1987 Carpentier et al.
4,648,881 A 3/1987 Carpentier et al.
4,655,218 A 4/1987 Kulik et al.
4,655,771 A 4/1987 Wallsten
4,662,885 A 5/1987 Dipisa, Jr.
4,665,906 A 5/1987 Jervis
4,680,031 A 7/1987 Alonso
4,692,164 A 9/1987 Dzemeshkevich et al.
4,705,516 A 11/1987 Barone et al.
4,710,192 A 12/1987 Liotta et al.
4,733,665 A 3/1988 Palmaz
4,755,181 A 7/1988 Igoe
4,759,758 A 7/1988 Gabbay
4,777,951 A 10/1988 Cribier et al.
4,787,899 A 11/1988 Lazarus
4,787,901 A 11/1988 Baykut
4,796,629 A 1/1989 Grayzel
4,819,751 A 4/1989 Shimada et al.
4,829,990 A 5/1989 Thuroff et al.
4,834,755 A 5/1989 Silvestrini et al.
4,851,001 A 7/1989 Taheri
4,856,516 A 8/1989 Hillstead
4,865,600 A 9/1989 Carpentier et al.
4,872,874 A 10/1989 Taheri
4,873,978 A 10/1989 Ginsburg
4,878,495 A 11/1989 Grayzel
4,878,906 A 11/1989 Lindemann et al.
4,883,458 A 11/1989 Shiber
4,885,005 A 12/1989 Nashef et al.
4,909,252 A 3/1990 Goldberger
4,917,102 A 4/1990 Miller et al.
4,922,905 A 5/1990 Strecker
4,927,426 A 5/1990 Dretler
4,954,126 A 9/1990 Wallsten
4,966,604 A 10/1990 Reiss
4,969,890 A 11/1990 Sugita et al.
4,979,939 A 12/1990 Shiber
4,986,830 A 1/1991 Owens et al.
4,994,077 A 2/1991 Dobben
5,002,556 A 3/1991 Ishida et al.
5,002,559 A 3/1991 Tower
5,007,896 A 4/1991 Shiber
5,026,366 A 6/1991 Leckrone
5,032,128 A 7/1991 Alonso
5,037,434 A 8/1991 Lane
5,047,041 A 9/1991 Samuels
5,064,435 A 11/1991 Porter
5,080,668 A 1/1992 Bolz et al.
5,085,635 A 2/1992 Cragg
5,089,015 A 2/1992 Ross
5,132,473 A 7/1992 Furutaka et al.
5,141,494 A 8/1992 Danforth et al.
5,152,771 A 10/1992 Sabbaghian et al.
5,159,937 A 11/1992 Tremulis
5,161,547 A 11/1992 Tower
5,163,953 A 11/1992 Vince
5,167,628 A 12/1992 Boyles
5,209,741 A 5/1993 Spaeth
5,215,541 A 6/1993 Nashef et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

5,217,483	A	6/1993	Tower	5,840,081	A	11/1998	Andersen et al.
5,238,004	A	8/1993	Sahatjian et al.	5,843,158	A	12/1998	Lenker et al.
5,258,023	A	11/1993	Reger	5,855,597	A	1/1999	Jayaraman
5,258,042	A	11/1993	Mehta	5,855,601	A	1/1999	Bessler et al.
5,282,847	A	2/1994	Trescony et al.	5,855,602	A	1/1999	Angell
5,295,958	A	3/1994	Shturman	5,860,966	A	1/1999	Tower
5,332,402	A	7/1994	Teitelbaum	5,861,024	A	1/1999	Rashidi
5,336,258	A	8/1994	Quintero et al.	5,861,028	A	1/1999	Angell
5,350,398	A	9/1994	Pavcnik et al.	5,868,783	A	2/1999	Tower
5,360,444	A	11/1994	Kusuhara	5,873,906	A	2/1999	Lau et al.
5,370,685	A	12/1994	Stevens	5,876,419	A	3/1999	Carpenter et al.
5,389,106	A	2/1995	Tower	5,876,448	A	3/1999	Thompson et al.
5,397,351	A	3/1995	Pavcnik et al.	5,885,228	A	3/1999	Rosenman et al.
5,409,019	A	4/1995	Wilk	5,888,201	A	3/1999	Stinson et al.
5,411,552	A	5/1995	Andersen et al.	5,891,191	A	4/1999	Stinson
5,425,762	A	6/1995	Muller	5,895,399	A	4/1999	Barbut et al.
5,431,676	A	7/1995	Dubrul et al.	5,906,619	A	5/1999	Olson et al.
5,443,446	A	8/1995	Shturman	5,907,893	A	6/1999	Zadno-Azizi et al.
5,443,449	A	8/1995	Buelna	5,910,154	A	6/1999	Tsugita et al.
5,443,477	A	8/1995	Marin et al.	5,911,734	A	6/1999	Tsugita et al.
5,443,495	A	8/1995	Buscemi et al.	5,925,063	A	7/1999	Khosravi
5,443,499	A	8/1995	Schmitt	5,944,738	A	8/1999	Amplatz et al.
5,476,506	A	12/1995	Lunn	5,954,766	A	9/1999	Zadno-Azizi et al.
5,476,510	A	12/1995	Eberhardt et al.	5,957,949	A	9/1999	Leonhardt et al.
5,480,423	A	1/1996	Ravenscroft et al.	5,968,070	A	10/1999	Bley et al.
5,480,424	A	1/1996	Cox	5,984,957	A	11/1999	Laptewicz, Jr. et al.
5,500,014	A	3/1996	Quijano et al.	5,984,959	A	11/1999	Robertson et al.
5,507,767	A	4/1996	Maeda et al.	5,993,469	A	11/1999	McKenzie et al.
5,534,007	A	7/1996	St. Germain et al.	5,997,557	A	12/1999	Barbut et al.
5,545,133	A	8/1996	Burns et al.	6,010,522	A	1/2000	Barbut et al.
5,545,209	A	8/1996	Roberts et al.	6,010,530	A	1/2000	Goicoechea
5,545,211	A	8/1996	An et al.	6,022,370	A	2/2000	Tower
5,545,214	A	8/1996	Stevens	6,027,520	A	2/2000	Tsugita et al.
5,549,665	A	8/1996	Vesely et al.	6,027,525	A	2/2000	Suh et al.
5,554,185	A	9/1996	Block et al.	6,042,554	A	3/2000	Rosenman et al.
5,571,175	A	11/1996	Vanney et al.	6,042,598	A	3/2000	Tsugita et al.
5,571,215	A	11/1996	Serman et al.	6,042,607	A	3/2000	Williamson, IV et al.
5,573,520	A	11/1996	Schwartz et al.	6,051,014	A	4/2000	Jang
5,575,818	A	11/1996	Pinchuk	6,059,827	A	5/2000	Fenton, Jr.
5,591,185	A	1/1997	Kilmer et al.	6,074,418	A	6/2000	Buchanan et al.
5,591,195	A	1/1997	Taheri et al.	6,093,203	A	7/2000	Uflacker
5,607,464	A	3/1997	Trescony et al.	6,096,074	A	8/2000	Pedros
5,609,626	A	3/1997	Quijano et al.	6,123,723	A	9/2000	Konya et al.
5,645,559	A	7/1997	Hachtman et al.	6,132,473	A	10/2000	Williams et al.
5,662,671	A	9/1997	Barbut et al.	6,139,510	A	10/2000	Palermo
5,667,523	A	9/1997	Bynon et al.	6,142,987	A	11/2000	Tsugita
5,674,277	A	10/1997	Freitag	6,146,366	A	11/2000	Schachar
5,693,083	A	12/1997	Baker et al.	6,162,245	A	12/2000	Jayaraman
5,693,310	A	12/1997	Gries et al.	6,165,200	A	12/2000	Tsugita et al.
5,695,498	A	12/1997	Tower	6,165,209	A	12/2000	Patterson et al.
5,709,713	A	1/1998	Evans et al.	6,168,579	B1	1/2001	Tsugita
5,713,951	A	2/1998	Garrison et al.	6,168,614	B1	1/2001	Andersen et al.
5,713,953	A	2/1998	Vallana et al.	6,171,327	B1	1/2001	Daniel et al.
5,716,370	A	2/1998	Williamson, IV et al.	6,171,335	B1	1/2001	Wheatley et al.
5,716,417	A	2/1998	Girard et al.	6,179,859	B1	1/2001	Bates et al.
5,720,391	A	2/1998	Dohm et al.	6,187,016	B1	2/2001	Hedges et al.
5,725,549	A	3/1998	Lam	6,197,053	B1	3/2001	Cosgrove et al.
5,728,068	A	3/1998	Leone et al.	6,200,336	B1	3/2001	Pavcnik et al.
5,733,325	A	3/1998	Robinson et al.	6,214,036	B1	4/2001	Letendre et al.
5,735,842	A	4/1998	Krueger et al.	6,221,006	B1	4/2001	Dubrul et al.
5,749,890	A	5/1998	Shaknovich	6,221,091	B1	4/2001	Khosravi
5,755,783	A	5/1998	Stobie et al.	6,221,096	B1 *	4/2001	Aiba A61F 2/86 606/108
5,756,476	A	5/1998	Epstein et al.	6,221,100	B1	4/2001	Strecker
5,769,812	A	6/1998	Stevens et al.	6,231,544	B1	5/2001	Tsuigita et al.
5,772,609	A	6/1998	Nguyen et al.	6,231,551	B1	5/2001	Barbut
5,800,456	A	9/1998	Maeda et al.	6,241,757	B1	6/2001	An et al.
5,800,531	A	9/1998	Cosgrove et al.	6,245,102	B1	6/2001	Jayaraman
5,807,405	A	9/1998	Vanney et al.	6,251,135	B1	6/2001	Stinson et al.
5,817,126	A	10/1998	Imran	6,258,114	B1	7/2001	Konya et al.
5,824,041	A	10/1998	Lenker et al.	6,258,115	B1	7/2001	Dubrul
5,824,043	A	10/1998	Cottone, Jr.	6,258,120	B1	7/2001	McKenzie et al.
5,824,053	A	10/1998	Khosravi et al.	6,258,129	B1	7/2001	Dybdal et al.
5,824,055	A	10/1998	Spiridigliozzi et al.	6,267,783	B1	7/2001	Letendre et al.
5,824,056	A	10/1998	Rosenberg	6,270,513	B1	8/2001	Tsugita et al.
5,824,064	A	10/1998	Taheri	6,277,555	B1	8/2001	Duran et al.
				6,299,637	B1	10/2001	Shaolian et al.
				6,302,906	B1	10/2001	Goicoechea et al.
				6,309,417	B1	10/2001	Spence et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,319,281 B1	11/2001	Patel	6,695,865 B2	2/2004	Boyle et al.
6,327,772 B1	12/2001	Zadno-Azizi et al.	6,702,851 B1	3/2004	Chinn et al.
6,336,934 B1	1/2002	Gilson et al.	6,712,842 B1	3/2004	Gifford, III et al.
6,336,937 B1	1/2002	Vonesh et al.	6,712,843 B2	3/2004	Elliott
6,338,735 B1	1/2002	Stevens	6,714,842 B1	3/2004	Ito
6,346,116 B1	2/2002	Brooks et al.	6,719,789 B2	4/2004	Cox
6,348,063 B1	2/2002	Yassour et al.	6,723,116 B2	4/2004	Taheri
6,352,554 B2	3/2002	De Paulis	6,730,118 B2	5/2004	Spenser et al.
6,352,708 B1	3/2002	Duran et al.	6,730,377 B2	5/2004	Wang
6,361,545 B1	3/2002	Macoviak et al.	6,733,525 B2 *	5/2004	Yang A61F 2/2418 623/1.24
6,363,938 B2	4/2002	Saadat et al.	6,736,846 B2	5/2004	Cox
6,364,895 B1	4/2002	Greenhalgh	6,752,828 B2	6/2004	Thornton
6,371,970 B1	4/2002	Khosravi et al.	6,755,854 B2	6/2004	Gillick et al.
6,371,983 B1	4/2002	Lane	6,758,855 B2	7/2004	Fulton, III et al.
6,379,383 B1	4/2002	Palmas et al.	6,764,503 B1	7/2004	Ishimaru
6,398,807 B1	6/2002	Chouinard et al.	6,764,509 B2	7/2004	Chinn et al.
6,402,736 B1	6/2002	Brown et al.	6,767,345 B2	7/2004	St. Germain et al.
6,409,750 B1	6/2002	Hydoh et al.	6,769,434 B2	8/2004	Liddicoat et al.
6,416,510 B1	7/2002	Altman et al.	6,773,454 B2	8/2004	Wholey et al.
6,425,916 B1	7/2002	Garrison et al.	6,776,791 B1	8/2004	Stallings et al.
6,440,164 B1	8/2002	DiMatteo et al.	6,786,925 B1 *	9/2004	Schoon A61B 17/064 623/2.11
6,454,799 B1	9/2002	Schreck	6,790,229 B1	9/2004	Berrekouw
6,458,153 B1	10/2002	Bailey et al.	6,790,230 B2	9/2004	Beyersdorf et al.
6,461,382 B1	10/2002	Cao	6,790,237 B2	9/2004	Stinson
6,468,303 B1	10/2002	Amplatz et al.	6,792,979 B2	9/2004	Konya et al.
6,468,660 B2	10/2002	Ogle et al.	6,797,002 B2	9/2004	Spence et al.
6,475,239 B1	11/2002	Campbell et al.	6,814,746 B2	11/2004	Thompson et al.
6,482,228 B1	11/2002	Norred	6,821,297 B2	11/2004	Snyders
6,485,501 B1	11/2002	Green	6,830,585 B1	12/2004	Artof et al.
6,485,502 B2	11/2002	Don Michael et al.	6,837,901 B2	1/2005	Rabkin et al.
6,488,704 B1	12/2002	Connelly et al.	6,840,957 B2	1/2005	DiMatteo et al.
6,494,909 B2	12/2002	Greenhalgh	6,843,802 B1	1/2005	Villalobos et al.
6,503,272 B2	1/2003	Duerig et al.	6,849,085 B2	2/2005	Marton
6,508,803 B1	1/2003	Horikawa et al.	6,863,668 B2	3/2005	Gillespie et al.
6,508,833 B2	1/2003	Pavcnik et al.	6,866,650 B2	3/2005	Stevens et al.
6,527,800 B1	3/2003	McGuckin, Jr. et al.	6,866,669 B2	3/2005	Buzzard et al.
6,530,949 B2	3/2003	Konya et al.	6,872,223 B2	3/2005	Roberts et al.
6,530,952 B2 *	3/2003	Vesely A61F 2/2409 623/1.24	6,872,226 B2	3/2005	Cali et al.
6,537,297 B2	3/2003	Tsugita et al.	6,875,231 B2	4/2005	Anduiza et al.
6,540,768 B1	4/2003	Diaz et al.	6,881,220 B2	4/2005	Edwin et al.
6,562,058 B2	5/2003	Seguin et al.	6,887,266 B2	5/2005	Williams et al.
6,569,196 B1 *	5/2003	Vesely A61F 2/2409 623/1.24	6,890,340 B2	5/2005	Duane
6,572,643 B1	6/2003	Gharibadeh	6,893,459 B1 *	5/2005	Macoviak A61F 2/2403 623/2.11
6,585,766 B1	7/2003	Huynh et al.	6,893,460 B2	5/2005	Spenser et al.
6,592,546 B1	7/2003	Barbut et al.	6,905,743 B1	6/2005	Chen et al.
6,592,614 B2	7/2003	Lenker et al.	6,908,481 B2	6/2005	Cribier
6,605,112 B1	8/2003	Moll et al.	6,911,036 B2	6/2005	Douk et al.
6,610,077 B1	8/2003	Hancock et al.	6,911,043 B2	6/2005	Myers et al.
6,616,682 B2	9/2003	Joergensen et al.	6,936,058 B2	8/2005	Forde et al.
6,622,604 B1	9/2003	Chouinard et al.	6,936,067 B2	8/2005	Buchanan
6,623,518 B2	9/2003	Thompson et al.	6,939,352 B2	9/2005	Buzzard et al.
6,623,521 B2	9/2003	Steinke et al.	6,951,571 B1 *	10/2005	Srivastava A61F 2/2418 623/1.24
6,632,243 B1	10/2003	Zadno-Azizi et al.	6,953,332 B1	10/2005	Kurk et al.
6,635,068 B1	10/2003	Dubrul et al.	6,964,673 B2	11/2005	Tsugita et al.
6,635,079 B2	10/2003	Unsworth et al.	6,969,395 B2	11/2005	Eskuri
6,652,571 B1	11/2003	White et al.	6,972,025 B2	12/2005	WasDyke
6,652,578 B2	11/2003	Bailey et al.	6,974,464 B2	12/2005	Quijano et al.
6,663,588 B2	12/2003	DuBois et al.	6,974,474 B2	12/2005	Pavcnik et al.
6,663,663 B2	12/2003	Kim et al.	6,974,476 B2	12/2005	McGuckin, Jr. et al.
6,669,724 B2	12/2003	Park et al.	6,979,350 B2	12/2005	Moll et al.
6,673,089 B1	1/2004	Yassour et al.	6,984,242 B2	1/2006	Campbell et al.
6,673,109 B2	1/2004	Cox	6,989,027 B2	1/2006	Allen et al.
6,676,668 B2	1/2004	Mercereau et al.	7,004,176 B2	2/2006	Lau
6,676,692 B2	1/2004	Rabkin et al.	7,011,681 B2 *	3/2006	Vesely A61F 2/2409 623/1.11
6,676,698 B2	1/2004	McGuckin, Jr. et al.	7,018,406 B2	3/2006	Seguin et al.
6,682,543 B2	1/2004	Barbut et al.	7,025,791 B2	4/2006	Levine et al.
6,682,558 B2	1/2004	Tu et al.	7,037,331 B2	5/2006	Mitelberg et al.
6,682,559 B2	1/2004	Myers et al.	7,041,132 B2 *	5/2006	Quijano A61F 2/2412 623/2.11
6,685,739 B2	2/2004	DiMatteo et al.	7,097,658 B2	8/2006	Oktay
6,689,144 B2	2/2004	Gerberding	7,097,659 B2 *	8/2006	Woolfson A61F 2/2409 623/2.38
6,689,164 B1	2/2004	Seguin	7,122,020 B2	10/2006	Mogul
6,692,512 B2	2/2004	Jang	7,125,418 B2	10/2006	Duran et al.
6,695,864 B2	2/2004	Macoviak et al.			

(56)	References Cited			8,133,270 B2 *	3/2012	Kheradvar	A61F 2/2418 623/1.26
	U.S. PATENT DOCUMENTS			8,136,659 B2	3/2012	Salahieh et al.	
				8,157,853 B2	4/2012	Laske et al.	
	7,141,063 B2	11/2006	White et al.	8,167,894 B2	5/2012	Miles et al.	
	7,166,097 B2	1/2007	Barbut	8,172,896 B2	5/2012	Mcnamara et al.	
	7,175,653 B2	2/2007	Gaber	8,182,528 B2	5/2012	Salahieh et al.	
	7,175,654 B2	2/2007	Bonsignore et al.	8,192,351 B2	6/2012	Fishler et al.	
	7,175,656 B2	2/2007	Khairkhahan	8,226,707 B2 *	7/2012	White	A61F 2/2412 623/1.12
	7,189,258 B2	3/2007	Johnson et al.				
	7,191,018 B2	3/2007	Gielen et al.	8,226,710 B2	7/2012	Nguyen et al.	
	7,201,772 B2	4/2007	Schwammenthal et al.	8,231,670 B2	7/2012	Salahieh et al.	
	7,235,093 B2	6/2007	Gregorich	8,236,049 B2	8/2012	Rowe et al.	
	7,258,696 B2	8/2007	Rabkin et al.	8,246,678 B2	8/2012	Salahieh et al.	
	7,267,686 B2	9/2007	DiMatteo et al.	8,252,051 B2	8/2012	Chau et al.	
	7,276,078 B2	10/2007	Spenser et al.	8,252,052 B2	8/2012	Salahieh et al.	
	7,322,932 B2	1/2008	Xie et al.	8,277,500 B2	10/2012	Schmid et al.	
	7,326,236 B2	2/2008	Andreas et al.	8,287,584 B2	10/2012	Salahieh et al.	
	7,329,279 B2	2/2008	Haug et al.	8,308,798 B2	11/2012	Pintor et al.	
	7,374,560 B2	5/2008	Ressemann et al.	8,317,858 B2	11/2012	Straubinger et al.	
	7,374,571 B2 *	5/2008	Pease	8,323,335 B2	12/2012	Rowe et al.	
				8,328,868 B2	12/2012	Paul et al.	
	7,381,219 B2 *	6/2008	Salahieh	8,343,213 B2 *	1/2013	Salahieh	A61F 2/2418 623/2.11
	7,381,220 B2	6/2008	Macoviak et al.	8,348,999 B2	1/2013	Kheradvar et al.	
	7,399,315 B2	7/2008	Iobbi	8,366,767 B2	2/2013	Zhang	
	7,445,631 B2	11/2008	Salahieh et al.	8,376,865 B2	2/2013	Forster et al.	
	7,470,285 B2	12/2008	Nugent et al.	8,377,117 B2	2/2013	Keidar et al.	
	7,473,417 B2	1/2009	Zeltinger et al.	8,398,708 B2	3/2013	Meiri et al.	
	7,491,232 B2	2/2009	Bolduc et al.	8,403,983 B2	3/2013	Quadri et al.	
	7,510,574 B2	3/2009	Lé et al.	8,414,644 B2	4/2013	Quadri et al.	
	7,524,330 B2	4/2009	Berrekouw	8,414,645 B2	4/2013	Dwork et al.	
	7,530,995 B2	5/2009	Quijano et al.	8,512,394 B2	8/2013	Schmid et al.	
	7,544,206 B2	6/2009	Cohn	8,523,936 B2	9/2013	Schmid et al.	
	7,569,071 B2 *	8/2009	Haverkost	8,540,762 B2	9/2013	Schmid et al.	
				8,545,547 B2	10/2013	Schmid et al.	
				8,579,962 B2 *	11/2013	Salahieh	A61F 2/2418 623/2.11
	7,601,159 B2	10/2009	Ewers et al.				
	7,622,276 B2	11/2009	Cunanan et al.	8,591,570 B2 *	11/2013	Revuelta	A61F 2/2418 623/1.26
	7,628,802 B2	12/2009	White et al.				
	7,628,803 B2	12/2009	Pavcnik et al.	8,603,160 B2 *	12/2013	Salahieh	A61F 2/2418 623/1.26
	7,632,298 B2	12/2009	Hijikema et al.				
	7,641,687 B2	1/2010	Chinn et al.	8,617,235 B2	12/2013	Schmid et al.	
	7,674,282 B2	3/2010	Wu et al.	8,617,236 B2	12/2013	Paul et al.	
	7,712,606 B2	5/2010	Salahieh et al.	8,623,074 B2	1/2014	Ryan	
	7,722,638 B2	5/2010	Deyette, Jr. et al.	8,623,076 B2	1/2014	Salahieh et al.	
	7,722,662 B2	5/2010	Steinke et al.	8,623,078 B2	1/2014	Salahieh et al.	
	7,722,666 B2 *	5/2010	Lafontaine	8,668,733 B2	3/2014	Haug et al.	
				8,828,078 B2	9/2014	Salahieh et al.	
	7,736,388 B2	6/2010	Goldfarb et al.	8,840,662 B2	9/2014	Salahieh et al.	
	7,748,389 B2	7/2010	Salahieh et al.	8,840,663 B2 *	9/2014	Salahieh	A61F 2/2418 623/2.1
	7,758,625 B2	7/2010	Wu et al.				
	7,763,065 B2	7/2010	Schmid et al.	8,852,272 B2 *	10/2014	Gross	A61F 2/2439 623/1.26
	7,771,467 B2 *	8/2010	Svensson				
				8,858,620 B2 *	10/2014	Salahieh	A61F 2/2418 623/1.26
	7,780,725 B2	8/2010	Haug et al.				
	7,799,065 B2	9/2010	Pappas	8,894,703 B2 *	11/2014	Salahieh	A61B 17/0644 623/2.11
	7,803,185 B2	9/2010	Gabbay				
	7,824,442 B2 *	11/2010	Salahieh	8,992,608 B2	3/2015	Haug et al.	
				8,998,976 B2	4/2015	Gregg et al.	
	7,824,443 B2 *	11/2010	Salahieh	9,005,273 B2	4/2015	Salahieh et al.	
				9,011,521 B2	4/2015	Haug et al.	
				9,039,756 B2 *	5/2015	White	A61F 2/2412 623/1.24
	7,833,262 B2	11/2010	McGuckin, Jr. et al.				
	7,846,204 B2	12/2010	Letac et al.	9,149,358 B2 *	10/2015	Tabor	A61F 2/2412
	7,857,845 B2	12/2010	Stacchino et al.	9,168,136 B2 *	10/2015	Yang	A61F 2/243
	7,892,292 B2	2/2011	Stack et al.	9,180,005 B1 *	11/2015	Lashinski	A61F 2/2445
	7,914,574 B2	3/2011	Schmid et al.	9,326,853 B2 *	5/2016	Olson	A61F 2/2418
	7,918,880 B2	4/2011	Austin	9,370,421 B2 *	6/2016	Crisostomo	A61B 17/00
	7,927,363 B2	4/2011	Perouse	9,393,115 B2 *	7/2016	Tabor	A61F 2/2412
	7,938,851 B2	5/2011	Olson et al.	9,492,276 B2 *	11/2016	Lee	A61F 2/2445
	7,947,071 B2	5/2011	Schmid et al.	9,532,872 B2 *	1/2017	Salahieh	A61B 17/0644
	7,959,666 B2	6/2011	Salahieh et al.	9,539,091 B2 *	1/2017	Yang	A61F 2/243
	7,959,672 B2	6/2011	Salahieh et al.				
	7,967,853 B2 *	6/2011	Eidenschink	2001/0002445 A1	5/2001	Vesely	
				2001/0007956 A1	7/2001	Letac et al.	
	7,988,724 B2	8/2011	Salahieh et al.	2001/0010017 A1	7/2001	Letac et al.	
	8,048,153 B2	11/2011	Salahieh et al.	2001/0021872 A1	9/2001	Bailey et al.	
	8,052,749 B2	11/2011	Salahieh et al.	2001/0025196 A1	9/2001	Chinn et al.	

(56)

References Cited

U.S. PATENT DOCUMENTS

2001/0032013	A1	10/2001	Marton	2003/0176884	A1	9/2003	Berrada et al.
2001/0039450	A1	11/2001	Pavcnik et al.	2003/0181850	A1	9/2003	Diamond et al.
2001/0041928	A1	11/2001	Pavcnik et al.	2003/0187495	A1	10/2003	Cully et al.
2001/0041930	A1	11/2001	Globerman et al.	2003/0191516	A1	10/2003	Weldon et al.
2001/0044634	A1	11/2001	Don Michael et al.	2003/0195609	A1	10/2003	Berenstein et al.
2001/0044652	A1	11/2001	Moore	2003/0199759	A1	10/2003	Richard
2001/0044656	A1	11/2001	Williamson, IV et al.	2003/0199913	A1	10/2003	Dubrul et al.
2002/0002396	A1	1/2002	Fulkerson	2003/0199971	A1	10/2003	Tower et al.
2002/0010489	A1	1/2002	Grayzel et al.	2003/0199972	A1	10/2003	Zadno-Azizi et al.
2002/0026233	A1	2/2002	Shaknovich	2003/0208224	A1	11/2003	Broome
2002/0029014	A1	3/2002	Jayaraman	2003/0212429	A1	11/2003	Keegan et al.
2002/0029981	A1	3/2002	Nigam	2003/0212452	A1	11/2003	Zadno-Azizi et al.
2002/0032480	A1	3/2002	Spence et al.	2003/0212454	A1	11/2003	Scott et al.
2002/0032481	A1	3/2002	Gabbay	2003/0216774	A1	11/2003	Larson
2002/0042651	A1	4/2002	Liddicoat et al.	2003/0225445	A1	12/2003	Derus et al.
2002/0052651	A1	5/2002	Myers et al.	2003/0229390	A1	12/2003	Ashton et al.
2002/0055767	A1*	5/2002	Forde A61B 17/0057 623/1.11	2003/0233117	A1	12/2003	Adams et al.
2002/0055769	A1	5/2002	Wang	2004/0019374	A1	1/2004	Hojeibane et al.
2002/0058995	A1	5/2002	Stevens	2004/0034411	A1*	2/2004	Quijano A61F 2/2412 623/2.11
2002/0077696	A1	6/2002	Zadno-Azizi et al.	2004/0039436	A1	2/2004	Spenser et al.
2002/0082609	A1	6/2002	Green	2004/0049224	A1	3/2004	Buehlmann et al.
2002/0095173	A1	7/2002	Mazzocchi et al.	2004/0049226	A1	3/2004	Keegan et al.
2002/0095209	A1	7/2002	Zadno-Azizi et al.	2004/0049262	A1*	3/2004	Obermiller A61F 2/2418 623/1.15
2002/0111674	A1	8/2002	Chouinard et al.	2004/0049266	A1	3/2004	Anduiza et al.
2002/0120323	A1*	8/2002	Thompson A61F 2/91 623/1.11	2004/0059409	A1	3/2004	Stenzel
2002/0120328	A1	8/2002	Pathak et al.	2004/0073198	A1	4/2004	Gilson et al.
2002/0123802	A1	9/2002	Snyders	2004/0082904	A1	4/2004	Houde et al.
2002/0138138	A1*	9/2002	Yang A61F 2/2418 623/2.18	2004/0082967	A1	4/2004	Broome et al.
2002/0151970	A1	10/2002	Garrison et al.	2004/0087982	A1	5/2004	Eskuri
2002/0161390	A1	10/2002	Mouw	2004/0088045	A1	5/2004	Cox
2002/0161392	A1	10/2002	Dubrul	2004/0093016	A1	5/2004	Root et al.
2002/0161394	A1	10/2002	Macoviak et al.	2004/0093060	A1	5/2004	Seguin et al.
2002/0165576	A1	11/2002	Boyle et al.	2004/0097788	A1	5/2004	Mourlas et al.
2002/0177766	A1	11/2002	Mogul	2004/0098022	A1	5/2004	Barone
2002/0183781	A1	12/2002	Casey et al.	2004/0098098	A1	5/2004	McGuckin, Jr. et al.
2002/0188341	A1	12/2002	Elliott	2004/0098099	A1	5/2004	McCullagh et al.
2002/0188344	A1	12/2002	Bolea et al.	2004/0098112	A1	5/2004	DiMatteo et al.
2002/0193871	A1	12/2002	Beyersdorf et al.	2004/0107004	A1	6/2004	Levine et al.
2003/0014104	A1	1/2003	Cribier	2004/0111096	A1	6/2004	Tu et al.
2003/0023303	A1	1/2003	Palmaz et al.	2004/0116951	A1	6/2004	Rosengart
2003/0028247	A1	2/2003	Cali	2004/0117004	A1	6/2004	Osborne et al.
2003/0036791	A1	2/2003	Philipp et al.	2004/0117009	A1	6/2004	Cali et al.
2003/0040736	A1	2/2003	Stevens et al.	2004/0122468	A1	6/2004	Yodfat et al.
2003/0040771	A1	2/2003	Hyodoh et al.	2004/0122516	A1	6/2004	Fogarty et al.
2003/0040772	A1	2/2003	Hyodoh et al.	2004/0127936	A1	7/2004	Salahieh et al.
2003/0040791	A1	2/2003	Oktay	2004/0127979	A1	7/2004	Wilson et al.
2003/0040792	A1	2/2003	Gabbay	2004/0133274	A1	7/2004	Webler et al.
2003/0050694	A1*	3/2003	Yang A61F 2/243 623/2.11	2004/0138694	A1	7/2004	Tran et al.
2003/0055495	A1*	3/2003	Pease A61F 2/2418 623/2.11	2004/0138742	A1	7/2004	Myers et al.
2003/0057156	A1	3/2003	Peterson et al.	2004/0138743	A1	7/2004	Myers et al.
2003/0060844	A1	3/2003	Borillo et al.	2004/0148018	A1	7/2004	Carpentier et al.
2003/0069492	A1	4/2003	Abrams et al.	2004/0148021	A1	7/2004	Cartledge et al.
2003/0069646	A1	4/2003	Stinson	2004/0153094	A1	8/2004	Dunfee et al.
2003/0070944	A1	4/2003	Nigam	2004/0158277	A1	8/2004	Lowe et al.
2003/0100918	A1	5/2003	Duane	2004/0167565	A1	8/2004	Beulke et al.
2003/0100919	A1	5/2003	Hopkins et al.	2004/0167620	A1	8/2004	Ortiz et al.
2003/0109924	A1	6/2003	Cribier	2004/0181140	A1	9/2004	Falwell et al.
2003/0109930	A1	6/2003	Bluni et al.	2004/0186558	A1	9/2004	Pavcnik et al.
2003/0114912	A1	6/2003	Sequin et al.	2004/0186563	A1	9/2004	Lobbi
2003/0114913	A1	6/2003	Spenser et al.	2004/0193261	A1	9/2004	Berrekouw
2003/0125795	A1	7/2003	Pavcnik et al.	2004/0199245	A1	10/2004	Lauterjung
2003/0130729	A1	7/2003	Paniagua et al.	2004/0204755	A1	10/2004	Robin
2003/0135257	A1	7/2003	Taheri	2004/0210304	A1	10/2004	Seguin et al.
2003/0144732	A1	7/2003	Cosgrove et al.	2004/0210306	A1	10/2004	Quijano et al.
2003/0149475	A1	8/2003	Hyodoh et al.	2004/0210307	A1	10/2004	Khairkhahan
2003/0149476	A1	8/2003	Damm et al.	2004/0215331	A1	10/2004	Chew et al.
2003/0149478	A1	8/2003	Figulla et al.	2004/0215333	A1	10/2004	Duran et al.
2003/0153974	A1	8/2003	Spenser et al.	2004/0215339	A1	10/2004	Drasler et al.
2003/0171803	A1	9/2003	Shimon	2004/0220655	A1*	11/2004	Swanson A61F 2/2487 623/1.11
				2004/0225321	A1	11/2004	Krolik et al.
				2004/0225353	A1	11/2004	McGuckin, Jr. et al.
				2004/0225354	A1	11/2004	Allen et al.
				2004/0225355	A1	11/2004	Stevens
				2004/0243221	A1	12/2004	Fawzi et al.
				2004/0254636	A1	12/2004	Flagle et al.
				2004/0260390	A1	12/2004	Sarac et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2005/0010287	A1	1/2005	Macoviak et al.	2005/0203616	A1	9/2005	Cribier
2005/0021136	A1	1/2005	Xie et al.	2005/0203617	A1	9/2005	Forster et al.
2005/0033398	A1	2/2005	Seguin	2005/0203618	A1	9/2005	Sharkawy et al.
2005/0033402	A1	2/2005	Cully et al.	2005/0209580	A1	9/2005	Freyman
2005/0043711	A1	2/2005	Corcoran et al.	2005/0228472	A1	10/2005	Case et al.
2005/0043757	A1	2/2005	Arad et al.	2005/0228495	A1	10/2005	Macoviak
2005/0043790	A1	2/2005	Seguin	2005/0234546	A1	10/2005	Nugent et al.
2005/0049692	A1	3/2005	Numamoto et al.	2005/0240200	A1	10/2005	Bergheim
2005/0049696	A1	3/2005	Siess et al.	2005/0240262	A1	10/2005	White
2005/0055088	A1	3/2005	Liddicoat et al.	2005/0251250	A1	11/2005	Verhoeven et al.
2005/0060016	A1	3/2005	Wu et al.	2005/0251251	A1	11/2005	Cribier
2005/0060029	A1	3/2005	Le et al.	2005/0261759	A1	11/2005	Lambrecht et al.
2005/0065594	A1	3/2005	DiMatteo et al.	2005/0267560	A1	12/2005	Bates
2005/0075584	A1	4/2005	Cali	2005/0283231	A1*	12/2005	Haug A61F 2/2418 623/2.11
2005/0075662	A1	4/2005	Pedersen et al.	2005/0283962	A1	12/2005	Boudjemline
2005/0075712	A1	4/2005	Biancucci et al.	2006/0004439	A1	1/2006	Spenser et al.
2005/0075717	A1	4/2005	Nguyen et al.	2006/0004442	A1	1/2006	Spenser et al.
2005/0075719	A1	4/2005	Bergheim	2006/0015168	A1	1/2006	Gunderson
2005/0075724	A1	4/2005	Svanidze et al.	2006/0058872	A1	3/2006	Salahieh et al.
2005/0075730	A1	4/2005	Myers et al.	2006/0149360	A1	7/2006	Schwammenthal et al.
2005/0075731	A1	4/2005	Artof et al.	2006/0155312	A1	7/2006	Levine et al.
2005/0085841	A1	4/2005	Eversull et al.	2006/0161249	A1	7/2006	Realyvasquez et al.
2005/0085842	A1	4/2005	Eversull et al.	2006/0173524	A1*	8/2006	Salahieh A61F 2/2439 623/1.11
2005/0085843	A1	4/2005	Opolski et al.	2006/0195183	A1	8/2006	Navia et al.
2005/0085890	A1	4/2005	Rasmussen et al.	2006/0212110	A1	9/2006	Osborne et al.
2005/0090846	A1	4/2005	Pedersen et al.	2006/0253191	A1	11/2006	Salahieh et al.
2005/0090890	A1	4/2005	Wu et al.	2006/0259134	A1	11/2006	Schwammenthal et al.
2005/0096692	A1	5/2005	Linder et al.	2006/0271166	A1	11/2006	Thill et al.
2005/0096734	A1	5/2005	Majercak et al.	2006/0287668	A1	12/2006	Fawzi et al.
2005/0096735	A1	5/2005	Hojeibane et al.	2006/0287717	A1	12/2006	Rowe et al.
2005/0096736	A1	5/2005	Osse et al.	2007/0010876	A1	1/2007	Salahieh et al.
2005/0096738	A1	5/2005	Cali et al.	2007/0010877	A1	1/2007	Salahieh et al.
2005/0100580	A1	5/2005	Osborne et al.	2007/0016286	A1*	1/2007	Herrmann A61F 2/243 623/2.11
2005/0107822	A1	5/2005	Wasdyke	2007/0055340	A1	3/2007	Pryor
2005/0113910	A1	5/2005	Paniagua et al.	2007/0061008	A1	3/2007	Salahieh et al.
2005/0131438	A1	6/2005	Cohn	2007/0088431	A1*	4/2007	Bourang A61F 2/2433 623/2.11
2005/0137683	A1	6/2005	Hezi-Yamit et al.	2007/0100427	A1	5/2007	Perouse
2005/0137686	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2007/0112355	A1*	5/2007	Salahieh A61F 2/2418 606/108
2005/0137687	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2007/0118214	A1	5/2007	Salahieh et al.
2005/0137688	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2007/0162107	A1	7/2007	Haug et al.
2005/0137689	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2007/0173918	A1	7/2007	Dreher et al.
2005/0137690	A1	6/2005	Salahieh et al.	2007/0203503	A1*	8/2007	Salahieh A61B 17/0644 606/108
2005/0137691	A1	6/2005	Salahieh et al.	2007/0203560	A1	8/2007	Forster et al.
2005/0137692	A1	6/2005	Haug et al.	2007/0244552	A1*	10/2007	Salahieh A61F 2/2418 623/2.11
2005/0137693	A1*	6/2005	Haug A61F 2/2415 623/2.11	2007/0265701	A1	11/2007	Gurskis et al.
2005/0137694	A1	6/2005	Haug et al.	2007/0288089	A1	12/2007	Gurskis et al.
2005/0137695	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2008/0004696	A1*	1/2008	Vesely A61F 2/2418 623/2.1
2005/0137696	A1	6/2005	Salahieh et al.	2008/0009940	A1	1/2008	Cribier
2005/0137697	A1	6/2005	Salahieh et al.	2008/0033541	A1	2/2008	Gelbart et al.
2005/0137698	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2008/0071363	A1	3/2008	Tuval et al.
2005/0137699	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2008/0082165	A1	4/2008	Wilson et al.
2005/0137701	A1	6/2005	Salahieh et al.	2008/0125859	A1	5/2008	Salahieh et al.
2005/0137702	A1	6/2005	Haug et al.	2008/0140189	A1	6/2008	Nguyen et al.
2005/0143807	A1	6/2005	Pavcnik et al.	2008/0177381	A1	7/2008	Navia et al.
2005/0143809	A1*	6/2005	Salahieh A61F 2/2418 623/2.11	2008/0188928	A1	8/2008	Salahieh et al.
2005/0149159	A1	7/2005	Andreas et al.	2008/0208328	A1	8/2008	Antocci et al.
2005/0165352	A1	7/2005	Henry et al.	2008/0208332	A1	8/2008	Lamphere et al.
2005/0165477	A1	7/2005	Anduiza et al.	2008/0221672	A1	9/2008	Lamphere et al.
2005/0165479	A1	7/2005	Drews et al.	2008/0234814	A1	9/2008	Salahieh et al.
2005/0182486	A1	8/2005	Gabbay	2008/0255661	A1	10/2008	Straubinger et al.
2005/0197694	A1	9/2005	Pai et al.	2008/0269878	A1	10/2008	Iobbi
2005/0197695	A1	9/2005	Stacchino et al.	2008/0288054	A1	11/2008	Pulnev et al.
2005/0203549	A1	9/2005	Realyvasquez	2009/0005863	A1	1/2009	Goetz et al.
2005/0203614	A1	9/2005	Forster et al.	2009/0030512	A1	1/2009	Thielen et al.
2005/0203615	A1	9/2005	Forster et al.	2009/0054969	A1*	2/2009	Salahieh A61F 2/2418 623/1.26
				2009/0076598	A1	3/2009	Salahieh et al.
				2009/0082844	A1*	3/2009	Zacharias A61F 2/07 623/1.13
				2009/0093877	A1	4/2009	Keidar et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0163951	A1	6/2009	Simmons et al.	
2009/0171456	A1	7/2009	Kveen et al.	
2009/0210052	A1 *	8/2009	Forster	A61F 2/2418 623/2.38
2009/0216312	A1	8/2009	Straubinger et al.	
2009/0222076	A1	9/2009	Figulla et al.	
2009/0264759	A1	10/2009	Byrd	
2009/0264997	A1	10/2009	Salahieh et al.	
2009/0299462	A1	12/2009	Fawzi et al.	
2009/0319037	A1 *	12/2009	Rowe	A61F 2/2418 623/2.11
2010/0004739	A1 *	1/2010	Vesely	A61F 2/2427 623/2.11
2010/0036479	A1	2/2010	Hill et al.	
2010/0049313	A1	2/2010	Alon et al.	
2010/0082089	A1	4/2010	Quadri et al.	
2010/0094399	A1	4/2010	Dorn et al.	
2010/0121434	A1	5/2010	Paul et al.	
2010/0161045	A1	6/2010	Righini	
2010/0185275	A1	7/2010	Richter et al.	
2010/0191320	A1	7/2010	Straubinger et al.	
2010/0191326	A1	7/2010	Alkhatib	
2010/0219092	A1	9/2010	Salahieh et al.	
2010/0249908	A1	9/2010	Chau et al.	
2010/0268332	A1	10/2010	Tuval et al.	
2010/0280495	A1	11/2010	Paul et al.	
2010/0298931	A1	11/2010	Quadri et al.	
2011/0040366	A1	2/2011	Goetz et al.	
2011/0098805	A1	4/2011	Dwork et al.	
2011/0257735	A1	10/2011	Salahieh et al.	
2011/0264191	A1	10/2011	Rothstein	
2011/0264196	A1	10/2011	Savage et al.	
2011/0264203	A1	10/2011	Dwork et al.	
2011/0276129	A1	11/2011	Salahieh et al.	
2011/0288634	A1	11/2011	Tuval et al.	
2011/0295363	A1	12/2011	Girard et al.	
2011/0319989	A1	12/2011	Lane et al.	
2012/0016469	A1	1/2012	Salahieh et al.	
2012/0016471	A1	1/2012	Salahieh et al.	
2012/0022633	A1	1/2012	Olson et al.	
2012/0022642	A1	1/2012	Haug et al.	
2012/0029627	A1	2/2012	Salahieh et al.	
2012/0041549	A1	2/2012	Salahieh et al.	
2012/0041550	A1 *	2/2012	Salahieh	A61F 2/2418 623/2.36
2012/0046740	A1	2/2012	Paul et al.	
2012/0053683	A1	3/2012	Salahieh et al.	
2012/0059447	A1	3/2012	Zilla et al.	
2012/0078357	A1	3/2012	Conklin	
2012/0089224	A1	4/2012	Haug et al.	
2012/0132547	A1	5/2012	Salahieh et al.	
2012/0179244	A1	7/2012	Schankereli et al.	
2012/0197379	A1	8/2012	Laske et al.	
2012/0303113	A1	11/2012	Benichou et al.	
2012/0303116	A1	11/2012	Gorman, III et al.	
2012/0330409	A1	12/2012	Haug et al.	
2013/0013057	A1	1/2013	Salahieh et al.	
2013/0018457	A1	1/2013	Gregg et al.	
2013/0030520	A1	1/2013	Lee et al.	
2013/0046373	A1	2/2013	Cartledge et al.	
2013/0066342	A1 *	3/2013	Dell	A61B 17/08 606/151
2013/0079867	A1	3/2013	Hoffman et al.	
2013/0079869	A1	3/2013	Straubinger et al.	
2013/0096664	A1	4/2013	Goetz et al.	
2013/0123796	A1	5/2013	Sutton et al.	
2013/0138207	A1	5/2013	Quadri et al.	
2013/0158656	A1	6/2013	Sutton et al.	
2013/0166017	A1	6/2013	Cartledge et al.	
2013/0184813	A1	7/2013	Quadri et al.	
2013/0190865	A1	7/2013	Anderson	
2013/0245752	A1	9/2013	Goetz et al.	
2013/0253640	A1	9/2013	Meiri et al.	
2013/0289698	A1	10/2013	Wang et al.	

2013/0296999	A1	11/2013	Burriesci et al.
2013/0304199	A1	11/2013	Sutton et al.
2013/0310917	A1	11/2013	Richter et al.
2013/0310923	A1	11/2013	Kheradvar et al.
2013/0325101	A1	12/2013	Goetz et al.
2013/0338755	A1	12/2013	Goetz et al.
2014/0018911	A1	1/2014	Zhou et al.
2014/0052239	A1	2/2014	Kong et al.
2014/0094904	A1	4/2014	Salahieh et al.
2014/0114405	A1	4/2014	Paul et al.
2014/0114406	A1	4/2014	Salahieh et al.
2014/0121766	A1	5/2014	Salahieh et al.
2014/0135912	A1	5/2014	Salahieh et al.
2014/0243962	A1	8/2014	Wilson et al.
2014/0243967	A1	8/2014	Salahieh et al.
2014/0249621	A1	9/2014	Eidenschink et al.
2014/0277414	A1	9/2014	Kheradvar
2014/0296962	A1	10/2014	Cartledge et al.
2015/0012085	A1	1/2015	Salahieh et al.
2015/0073541	A1	3/2015	Salahieh et al.
2015/0127094	A1	5/2015	Salahieh et al.

FOREIGN PATENT DOCUMENTS

DE	19546692	A1	6/1997
DE	19857887	A1	7/2000
DE	19907646	A1	8/2000
DE	10049812	A1	4/2002
DE	10049813	C1	4/2002
DE	10049814	A1	4/2002
DE	10049815	A1	4/2002
EP	0103546	B1	5/1988
EP	0144167	B1	11/1989
EP	0409929	B1	4/1997
EP	0850607	A1	7/1998
EP	0597967	B1	12/1999
EP	1000590	A1	5/2000
EP	1057459	A1	12/2000
EP	1057460	A1	12/2000
EP	1088529	A2	4/2001
EP	0937439	B1	9/2003
EP	1340473	A2	9/2003
EP	1356793	A2	10/2003
EP	1042045	B1	5/2004
EP	0819013	B1	6/2004
EP	1430853	A2	6/2004
EP	1472996	A1	11/2004
EP	1229864	B1	4/2005
EP	1059894	B1	7/2005
EP	1078610	B1	8/2005
EP	1570809	A1	9/2005
EP	1576937	A2	9/2005
EP	1582178	A2	10/2005
EP	1582179	A2	10/2005
EP	1469797	B1	11/2005
EP	1600121	A1	11/2005
EP	1156757	B1	12/2005
EP	1616531	A2	1/2006
EP	1605871	B1	7/2008
FR	2788217	A1	7/2000
GB	2056023	A	3/1981
GB	2398245	A	8/2004
SU	1271508	A1	11/1986
SU	1371700	A1	2/1988
WO	9117720	A1	11/1991
WO	9217118	A1	10/1992
WO	9301768	A1	2/1993
WO	9315693	A1	8/1993
WO	9504556	A2	2/1995
WO	9529640	A1	11/1995
WO	9614032	A1	5/1996
WO	9624306	A1	8/1996
WO	9640012	A1	12/1996
WO	9829057	A1	7/1998
WO	9836790	A1	8/1998
WO	9850103	A1	11/1998
WO	9857599	A2	12/1998
WO	9933414	A1	7/1999
WO	9940964	A1	8/1999

(56)

References Cited

FOREIGN PATENT DOCUMENTS

- | | | | |
|----|------------|----|---------|
| WO | 9944542 | A2 | 9/1999 |
| WO | 9947075 | A1 | 9/1999 |
| WO | 0009059 | A2 | 2/2000 |
| WO | 0041652 | A1 | 7/2000 |
| WO | 0044308 | A2 | 8/2000 |
| WO | 0044311 | A2 | 8/2000 |
| WO | 0044313 | A1 | 8/2000 |
| WO | 0045874 | A1 | 8/2000 |
| WO | 0047139 | A1 | 8/2000 |
| WO | 0049970 | A1 | 8/2000 |
| WO | 0067661 | A2 | 11/2000 |
| WO | 0105331 | A1 | 1/2001 |
| WO | 0108596 | A1 | 2/2001 |
| WO | 0110320 | A1 | 2/2001 |
| WO | 0110343 | A1 | 2/2001 |
| WO | 0135870 | A1 | 5/2001 |
| WO | 0149213 | A2 | 7/2001 |
| WO | 0154625 | A1 | 8/2001 |
| WO | 0162189 | A1 | 8/2001 |
| WO | 0164137 | A1 | 9/2001 |
| WO | 0176510 | A2 | 10/2001 |
| WO | 0197715 | A1 | 12/2001 |
| WO | 0236048 | A1 | 5/2002 |
| WO | 0241789 | A2 | 5/2002 |
| WO | 0243620 | A1 | 6/2002 |
| WO | 0247575 | A2 | 6/2002 |
| WO | 02056955 | A1 | 7/2002 |
| WO | 02100297 | A2 | 12/2002 |
| WO | 03003943 | A2 | 1/2003 |
| WO | 03003949 | A2 | 1/2003 |
| WO | 03011195 | A2 | 2/2003 |
| WO | 03028592 | A1 | 4/2003 |
| WO | 03030776 | A2 | 4/2003 |
| WO | 03037227 | A2 | 5/2003 |
| WO | 03047648 | A2 | 6/2003 |
| WO | 03015851 | B1 | 11/2003 |
| WO | 03094793 | A1 | 11/2003 |
| WO | 03094797 | A1 | 11/2003 |
| WO | 2004006803 | A1 | 1/2004 |
| WO | 2004006804 | A1 | 1/2004 |
| WO | 2004014256 | A1 | 2/2004 |
| WO | 2004019811 | A2 | 3/2004 |
| WO | 2004019817 | A1 | 3/2004 |
| WO | 2004021922 | A2 | 3/2004 |
| WO | 2004023980 | A2 | 3/2004 |
| WO | 2004026117 | A2 | 4/2004 |
| WO | 2004041126 | A1 | 5/2004 |
| WO | 2004043293 | A2 | 5/2004 |
| WO | 2004047681 | A1 | 6/2004 |
| WO | 2004058106 | A2 | 7/2004 |
| WO | 2004066876 | A1 | 8/2004 |
| WO | 2004082536 | A1 | 9/2004 |
| WO | 2004089250 | A1 | 10/2004 |
| WO | 2004089253 | A1 | 10/2004 |
| WO | 2004093728 | A2 | 11/2004 |
| WO | 2004105651 | A1 | 12/2004 |
| WO | 2005002466 | A2 | 1/2005 |
| WO | 2005004753 | A1 | 1/2005 |
| WO | 2005009285 | A2 | 2/2005 |
| WO | 2005011534 | A1 | 2/2005 |
| WO | 2005011535 | A2 | 2/2005 |
| WO | 2005023155 | A1 | 3/2005 |
| WO | 2005027790 | A1 | 3/2005 |
| WO | 2005046528 | A1 | 5/2005 |
| WO | 2005046529 | A1 | 5/2005 |
| WO | 2005048883 | A1 | 6/2005 |
| WO | 2005062980 | A2 | 7/2005 |
| WO | 2005065585 | A1 | 7/2005 |
| WO | 2005084595 | A1 | 9/2005 |
| WO | 2005087140 | A1 | 9/2005 |
| WO | 2005096993 | A1 | 10/2005 |
| WO | 2006005015 | A2 | 1/2006 |
| WO | 2006009690 | A1 | 1/2006 |
| WO | 2006027499 | A2 | 3/2006 |
| WO | 2006093795 | A1 | 9/2006 |
- | | | | |
|----|------------|----|---------|
| WO | 2006138391 | A2 | 12/2006 |
| WO | 2007009117 | A1 | 1/2007 |
| WO | 2007033093 | A2 | 3/2007 |
| WO | 2007035471 | A2 | 3/2007 |
| WO | 2007044285 | A2 | 4/2007 |
| WO | 2007053243 | A2 | 5/2007 |
| WO | 2007058847 | A2 | 5/2007 |
| WO | 2007092354 | A2 | 8/2007 |
| WO | 2007097983 | A2 | 8/2007 |
| WO | 2008028569 | A1 | 3/2008 |
| WO | 2008035337 | A2 | 3/2008 |
| WO | 2010042950 | A2 | 4/2010 |
| WO | 2010098857 | A1 | 9/2010 |
| WO | 2012116368 | A2 | 8/2012 |

OTHER PUBLICATIONS

- US 8,062,357, 11/2011, Salahieh et al. (withdrawn)
- US 8,075,614, 12/2011, Salahieh et al. (withdrawn)
- US 8,133,271, 03/2012, Salahieh et al. (withdrawn)
- US 8,211,170, 07/2012, Paul et al. (withdrawn)
- "Continuous", Collins English Dictionary, pp. 1-3, accessed Mar. 18, 2014.
- Andersen et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs." Euro. Heart J., 13:704-708, May 1992.
- Atwood et al., "Insertion of Heart Valves by Catheterization." Project Supervised by Prof. S. Muftu of Northeastern University 2001-2002: 36-40, May 30, 2002.
- Bodnar et al., "Replacement Cardiac Valves R Chapter 13: Extinct Cardiac Valve Prostheses" Pergamon Publishing Corporation. New York, 307-322, 1991.
- Boudjemline et al., "Percutaneous Implantation of a Biological Valve in the Aorta to Treat Aortic Valve Insufficiency—A Sheep Study." Med Sci. Monit., vol. 8, No. 4: BR113-116, Apr. 12, 2002.
- Boudjemline et al., "Percutaneous Implantation of a Valve in the Descending Aorta in Lambs." Euro. Heart J., 23: 1045-1049, Jul. 2002.
- Boudjemline et al., "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract: An Experimental Study." Journal of the American College of Cardiology, vol. 43(6): 1082-1087, Mar. 17, 2004.
- Boudjemline et al., "Percutaneous Valve Insertion: A New Approach?" J. of Thoracic and Cardio. Surg., 125(3): 741-743, Mar. 2003.
- Boudjemline et al., "Steps Toward Percutaneous Aortic Valve Replacement." Circulation, 105: 775-778, Feb. 12, 2002.
- Cribier et al., "Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis." J. of Am. Coll. of Cardio, 43(4): 698-703, Feb. 18, 2004.
- Cribier et al., "Percutaneous Transcatheter Implementation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description." Circulation, 106: 3006-3008, Dec. 10, 2002.
- Cribier et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case." Percutaneous Valve Technologies, Inc., 16 pages, Apr. 16, 2002.
- Ferrari et al., "Percutaneous Transvascular Aortic Valve Replacement with Self-Expanding Stent-Valve Device." Poster from the presentation given at SMIT 2000, 12th International Conference. Sep. 5, 2000.
- Hijazi, "Transcatheter Valve Replacement: A New Era of Percutaneous Cardiac Intervention Begins." J. of Am. College of Cardio., 43(6): 1088-1089, Mar. 17, 2004.
- Huber et al., "Do Valved Stents Compromise Coronary Flow?" European Journal of Cardio-thoracic Surgery, vol. 25: 754-759, Jan. 23, 2004.
- Knudsen et al., "Catheter-implanted prosthetic heart valves." Int'l J. of Art. Organs, 16(5): 253-262, May 1993.
- Kort et al., "Minimally Invasive Aortic Valve Replacement: Echocardiographic and Clinical Results." Am. Heart J., 142(3): 476-481, Sep. 2001.

(56)

References Cited**OTHER PUBLICATIONS**

- Love et al., "The Autogenous Tissue Heart Valve: Current Status." *Journal of Cardiac Surgery*, 6(4): 499-507, Mar. 1991.
- Lutter et al., "Percutaneous Aortic Valve Replacement: An Experimental Study. I. Studies on Implantation." *J. of Thoracic and Cardio. Surg.*, 123(4): 768-776, Apr. 2002.
- Moulopoulos et al., "Catheter-Mounted Aortic Valves." *Annals of Thoracic Surg.*, 11(5): 423-430, May 1971.
- Paniagua et al., "Percutaneous Heart Valve in the Chronic in Vitro Testing Model." *Circulation*, 106: e51-e52, Sep. 17, 2002.
- Paniagua et al., "Heart Watch." Texas Heart Institute. Edition: 8 pages, Spring, 2004.
- Pavcnik et al., "Percutaneous Bioprosthetic Venous Valve: A Long-term Study in Sheep." *J. of Vascular Surg.*, 35(3): 598-603, Mar. 2002.
- Phillips et al., "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency." *Annals of Thoracic Surg.*, 21(2): 134-136, Feb. 1976.
- Sochman et al., "Percutaneous Transcatheter Aortic Disc Valve Prosthesis Implantation: A Feasibility Study." *Cardiovasc. Intervent. Radiol.*, 23: 384-388, Sep. 2000.
- Stuart, "In Heart Valves, a Brave, New Non-Surgical World." *Start-Up*. 9-17, Feb. 2004.
- Vahanian et al., "Percutaneous Approaches to Valvular Disease." *Circulation*, 109: 1572-1579, Apr. 6, 2004.
- Van Herwerden et al., "Percutaneous Valve Implantation: Back to the Future?" *Euro. Heart J.*, 23(18): 1415-1416, Sep. 2002.
- Zhou et al., "Self-expandable Valved Stent of Large Size: Off-Bypass Implantation in Pulmonary Position." *Eur. J. Cardiothorac.*, 24: 212-216, Aug. 2003.
- Examiner's First Report on AU Patent Application No. 2011202667, dated May 17, 2012.
- "A Matter of Size." Triennial Review of the National Nanotechnology Initiative, the National Academies Press, Washington DC, v-13, <http://www.nap.edu/catalog/11752/a-matter-of-size-triennial-review-of-the-national-nanotechnology>, 2006.
- Atwood et al., "Insertion of Heart Valves by Catheterization." The Capstone Design Course Report. MIME 1501-1502. Technical Design Report Northeastern University, pp. 1-93, Nov. 5, 2007.
- Supplemental Search Report from EP Patent Office, EP Application No. 04813777.2, dated Aug. 19, 2011.
- Supplemental Search Report from EP Patent Office, EP Application No. 04815634.3, dated Aug. 19, 2011.
- Cunanan et al., "Tissue Characterization and Calcification Potential of Commercial Bioprosthetic Heart Valves." *Ann. Thorac. Surg.*, S417-421, May 15, 2001.
- Cunliffe et al., "Glutaraldehyde Inactivation of Exotic Animal Viruses in Swine Heart Tissue." *Applied and Environmental Microbiology*, Greenport, New York, 37(5): 1044-1046, May 1979.
- EP Search Report for EP Application No. 06824992.9, dated Aug. 10, 2011.
- "Heart Valve Materials—Bovine (cow)." Equine & Porcine Pericardium, Maverick Biosciences Pty. Lt, <http://maverickbio.com/biological-medical-device-materials?php?htm>. 2009.
- Helmus, "Mechanical and Bioprosthetic Heart Valves in Biomaterials for Artificial Organs." Woodhead Publishing Limited: 114-162, 2011.
- Houriha et al., "Transcatheter Umbrella Closure of Valvular and Paravalvular Leaks." *JACC*, Boston, Massachusetts, 20(6): 1371-1377, Nov. 15, 1992.
- Laborde et al., "Percutaneous Implantation of the Corevalve Aortic Valve Prosthesis for Patients Presenting High Risk for Surgical Valve Replacement." *EuroIntervention*: 472-474, Feb. 2006.
- Levy, "Mycobacterium Chelonae Infection of Porcine Heart Valves." *The New England Journal of Medicine*, Washington DC, 297(12), Sep. 22, 1977.
- Supplemental Search Report from EP Patent Office, EP Application No. 05758878.2, dated Oct. 24, 2011.
- "Pericardial Heart Valves." Edwards Lifesciences, Cardiovascular Surgery FAQ, <http://www.edwards.com/products/cardiovascularsurgeryfaq.htm>, Nov. 14, 2010.
- Southern Lights Biomaterials Homepage, <http://www.slv.co.nz/>, Jan. 7, 2011.
- Stassano. "Mid-term Results of the Valve-on-Valve Technique for Bioprosthetic Failure." *European Journal of Cardiothoracic Surgery*: vol. 18, 453-457, Oct. 2000.
- Topol. "Percutaneous Expandable Prosthetic Valves." *Textbook of Interventional Cardiology*, W.B. Saunders Company, 2: 1268-1276, 1994.

* cited by examiner

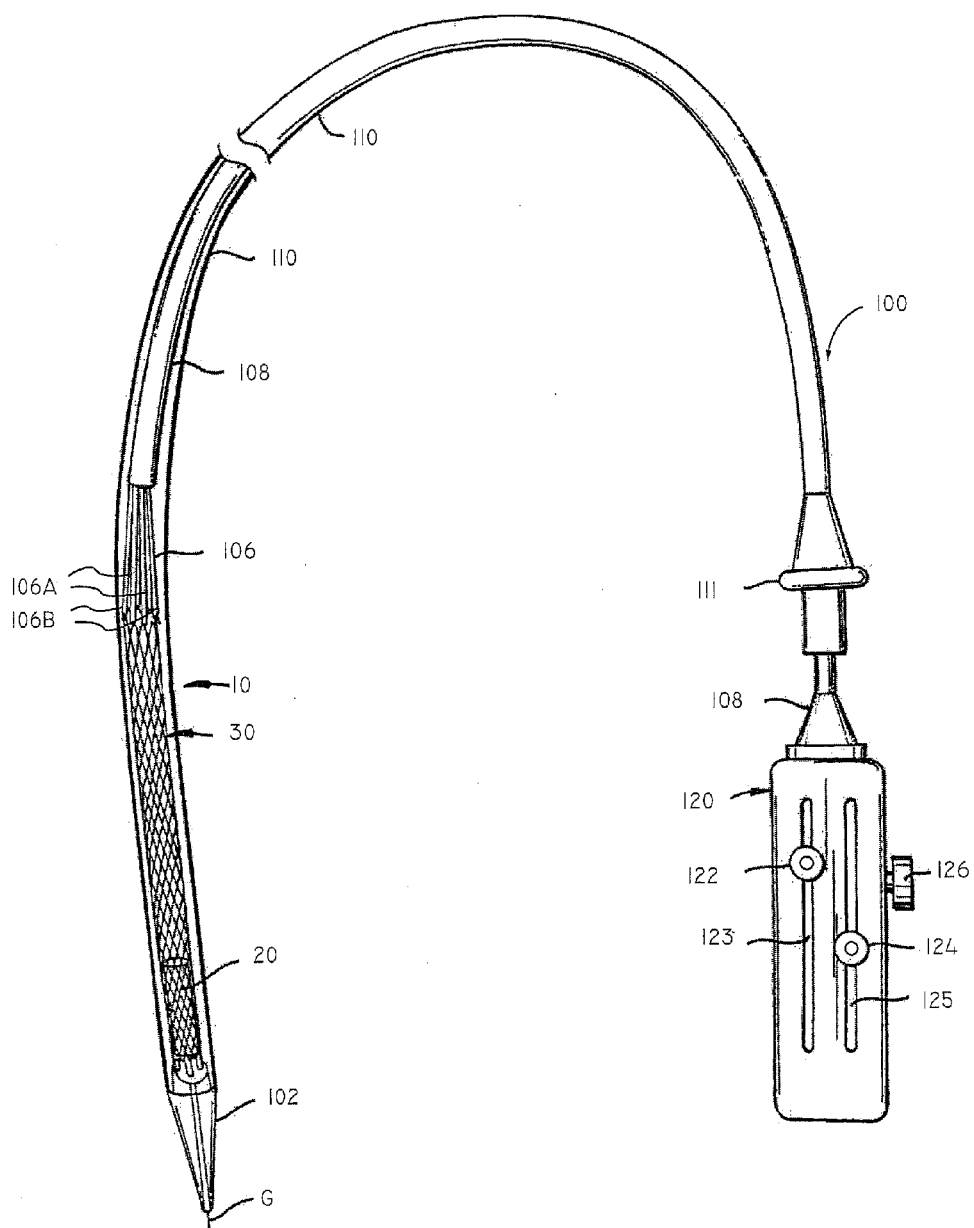


FIG 1A

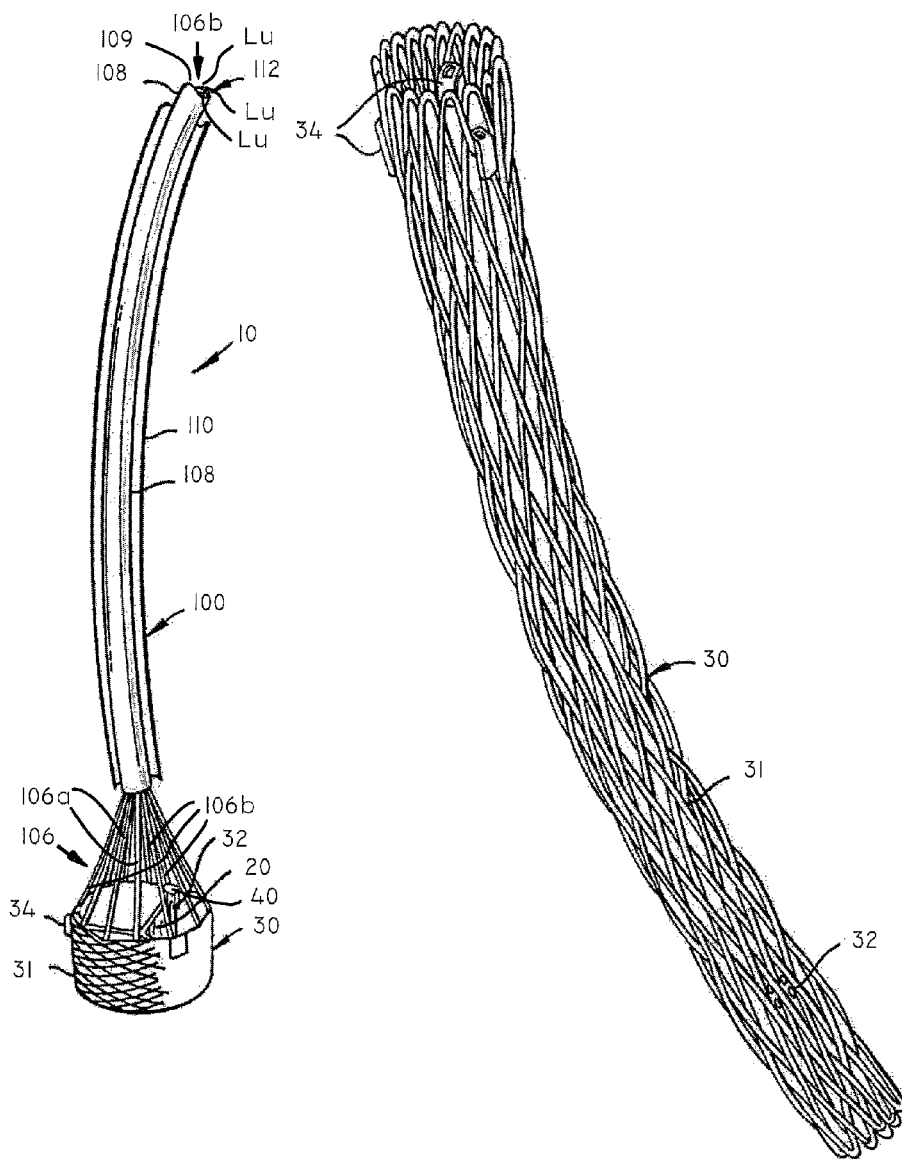


FIG 1B

FIG 2A

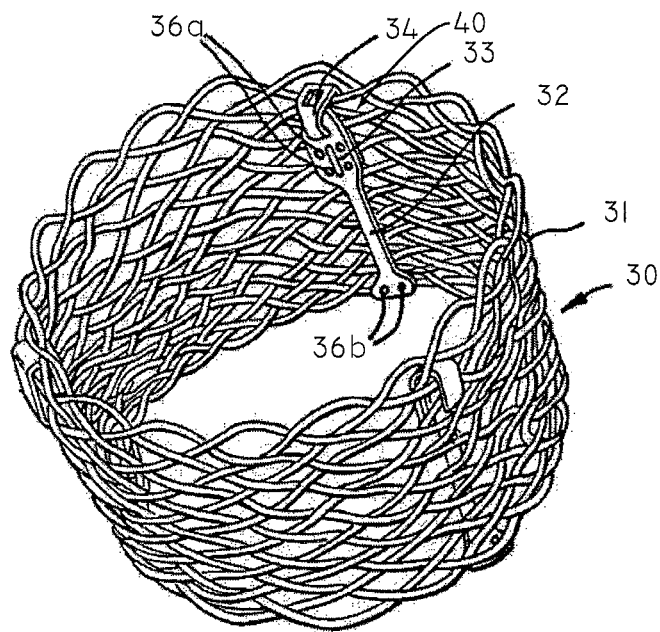


FIG 2B

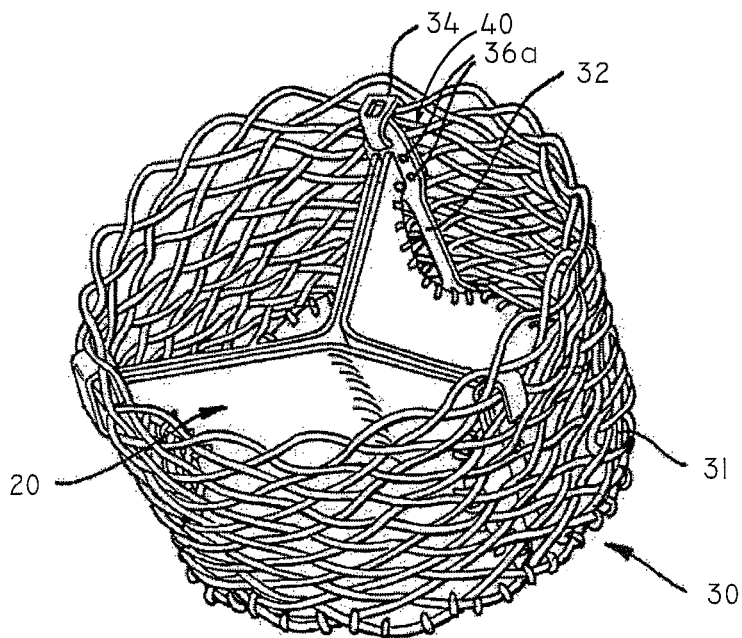


FIG 2C

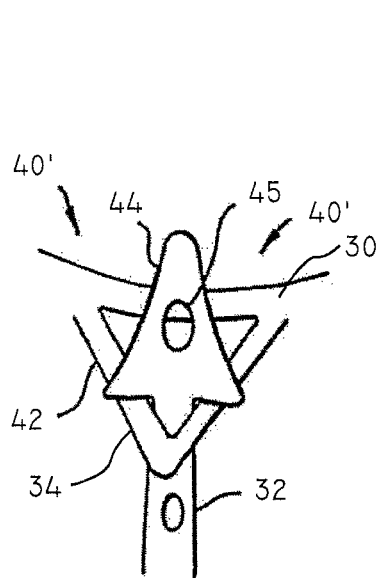


FIG 2D

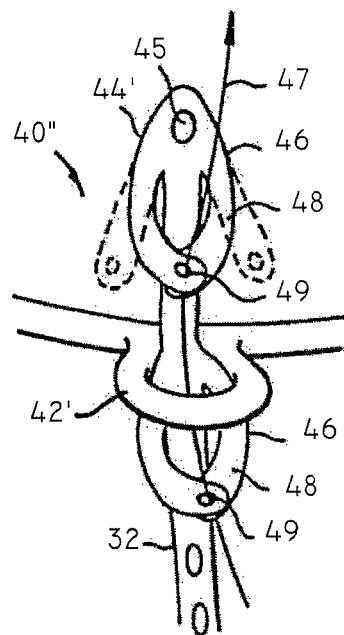


FIG 2E

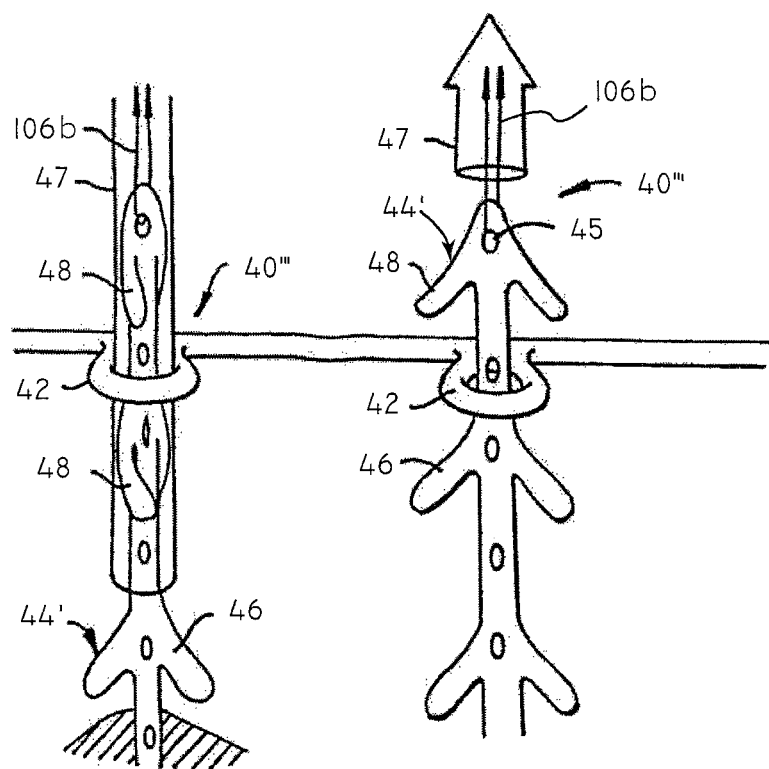


FIG 2F

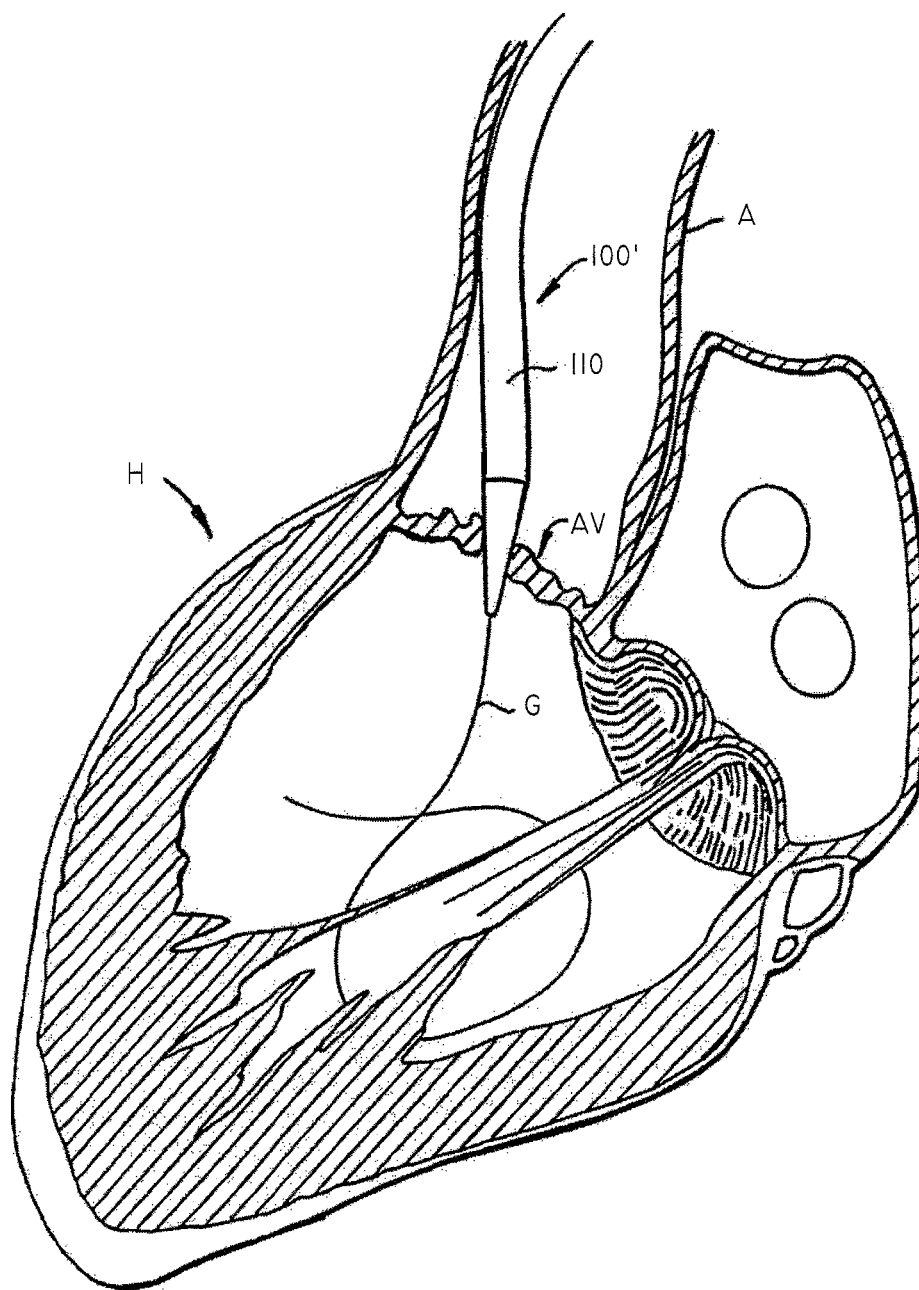


FIG 3A

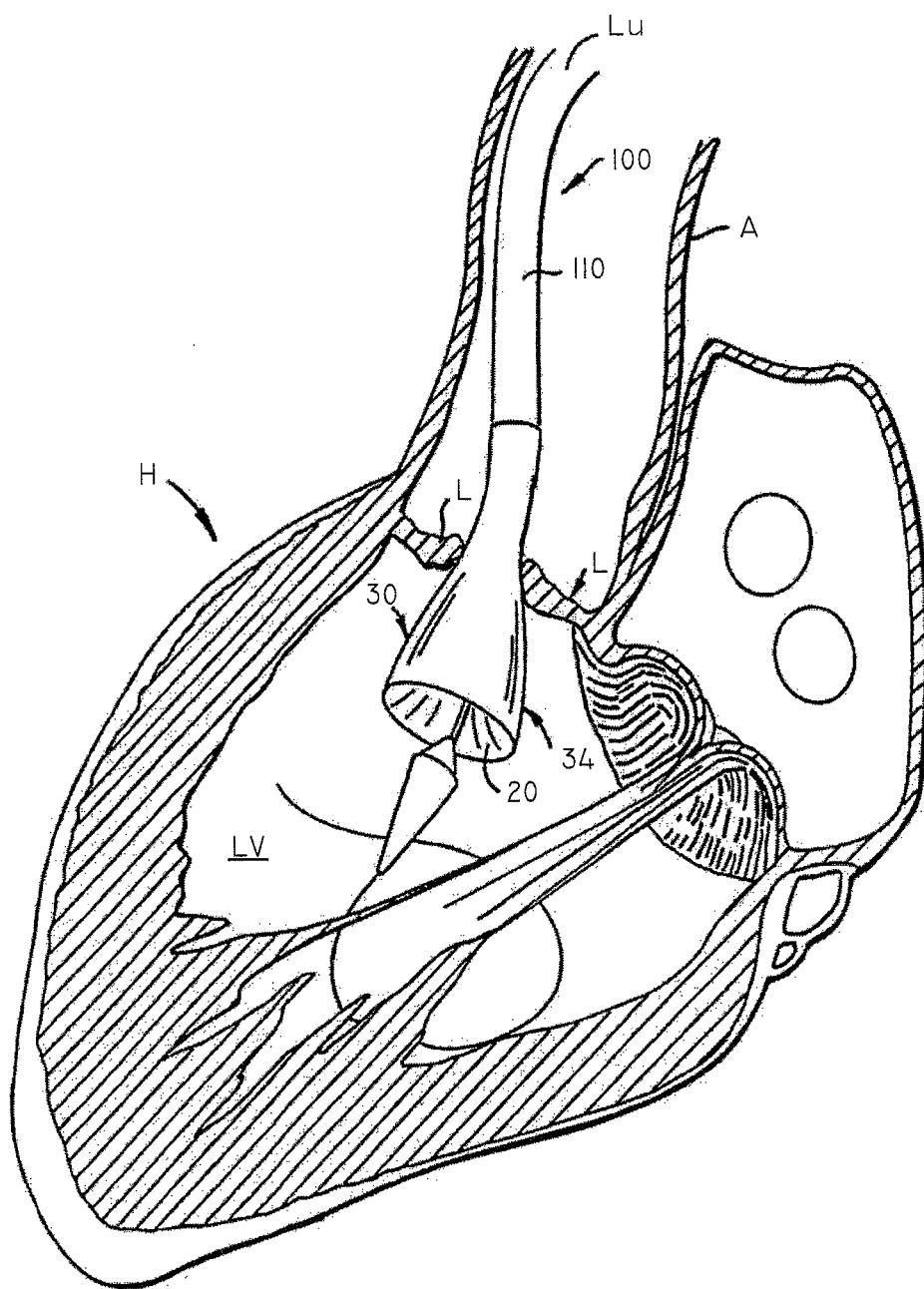


FIG 3B

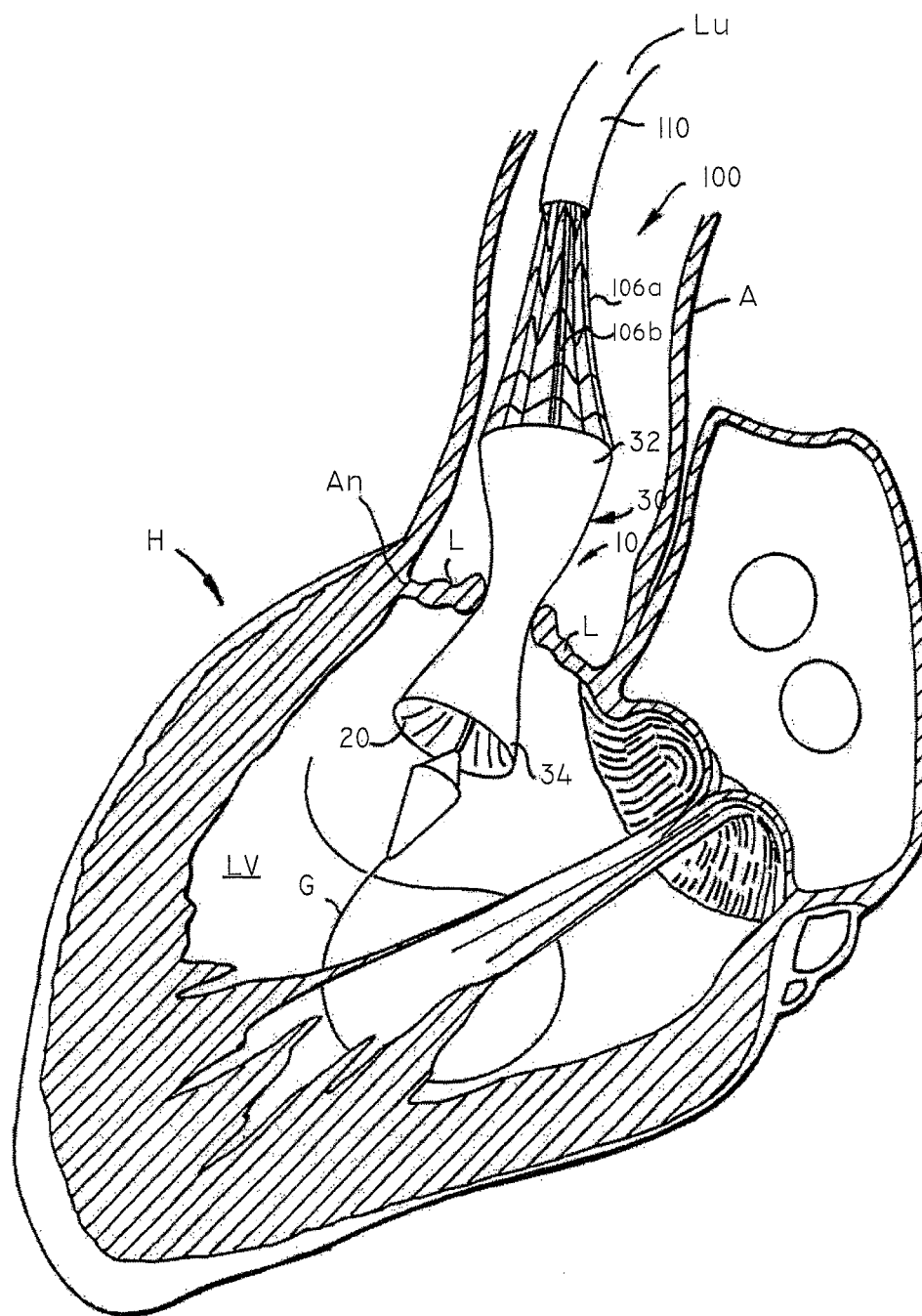


FIG 3C

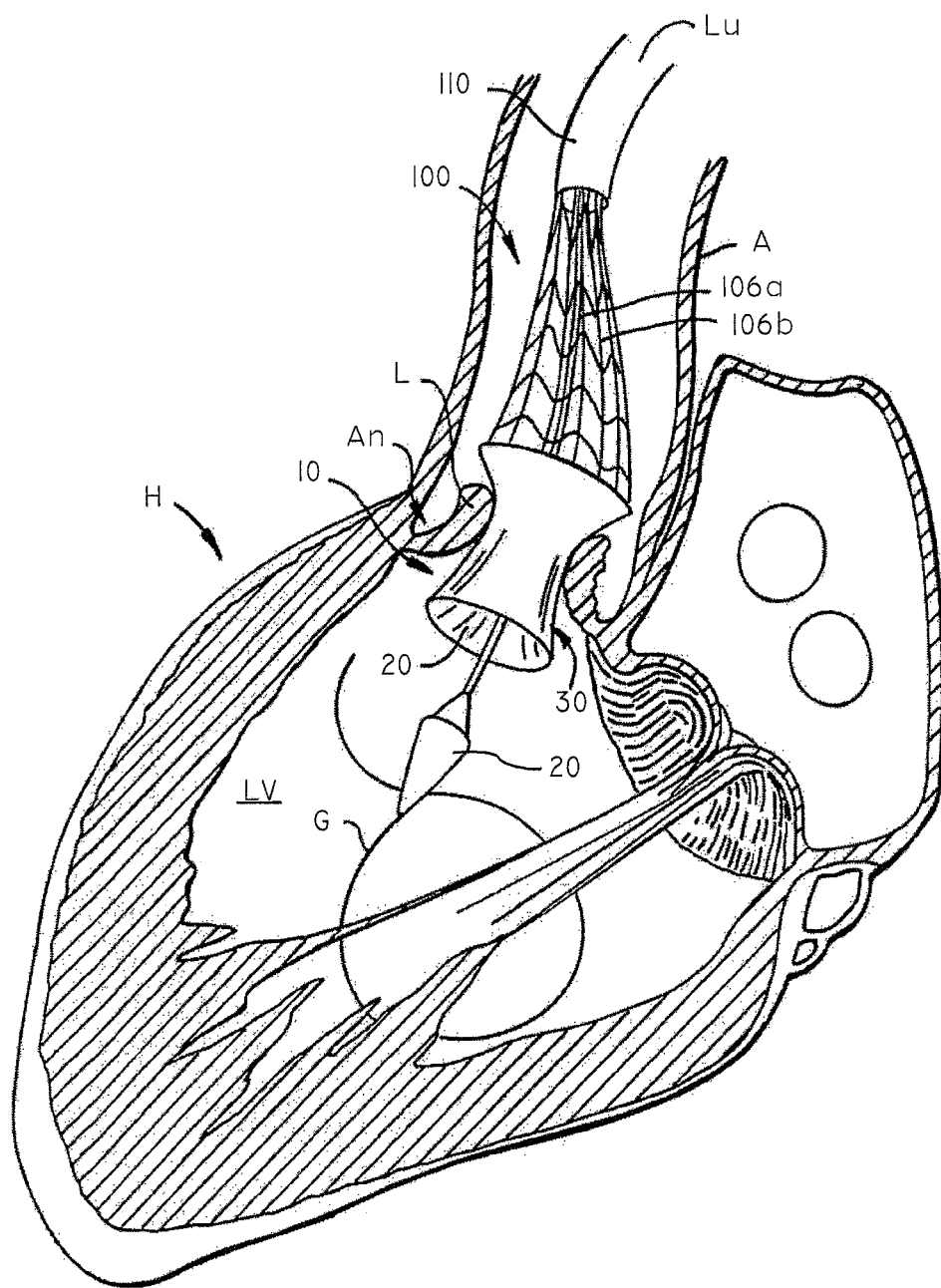


FIG 3D

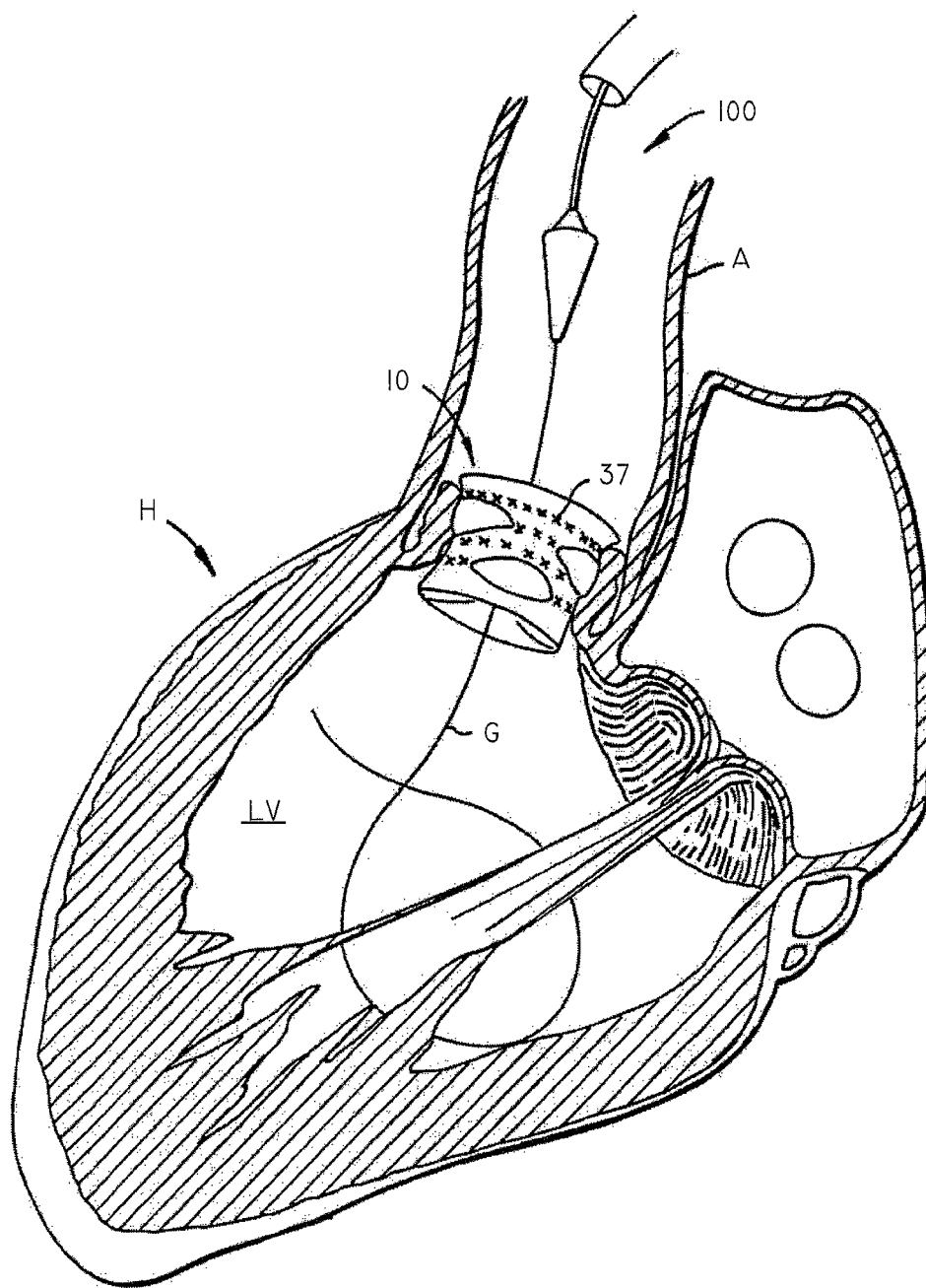


FIG 3E

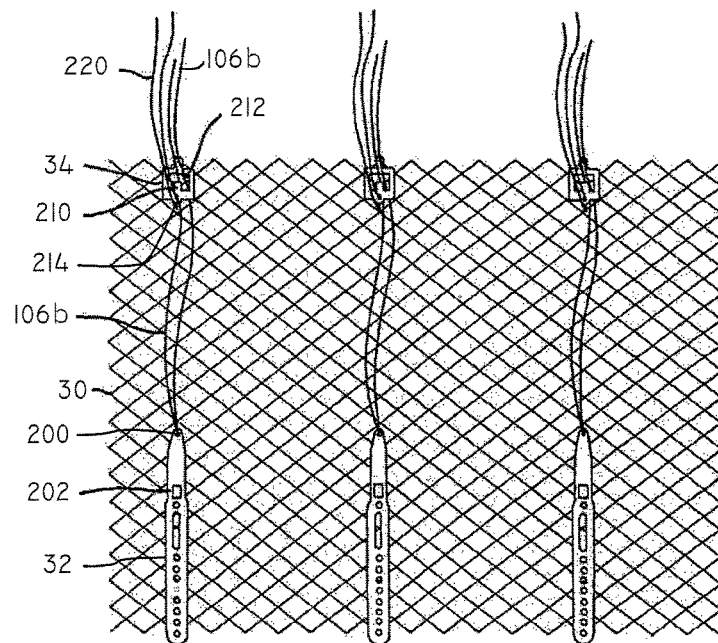


FIG 4A

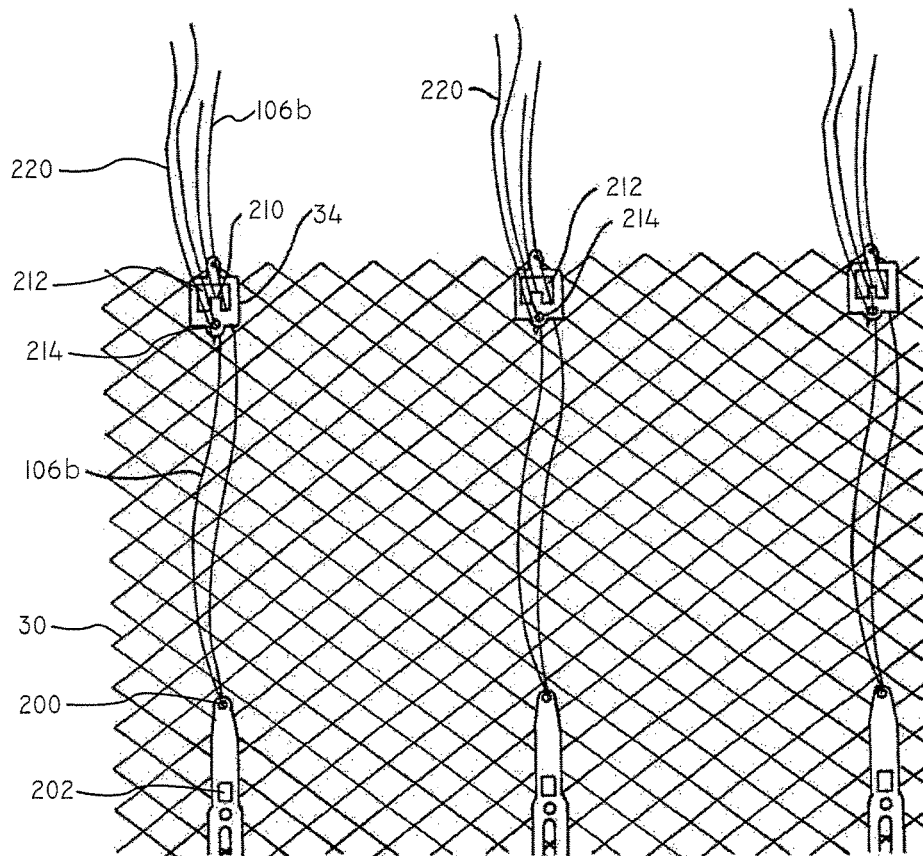


FIG 4B

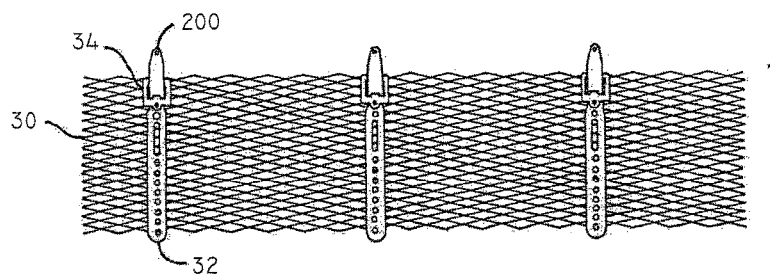


FIG 5A

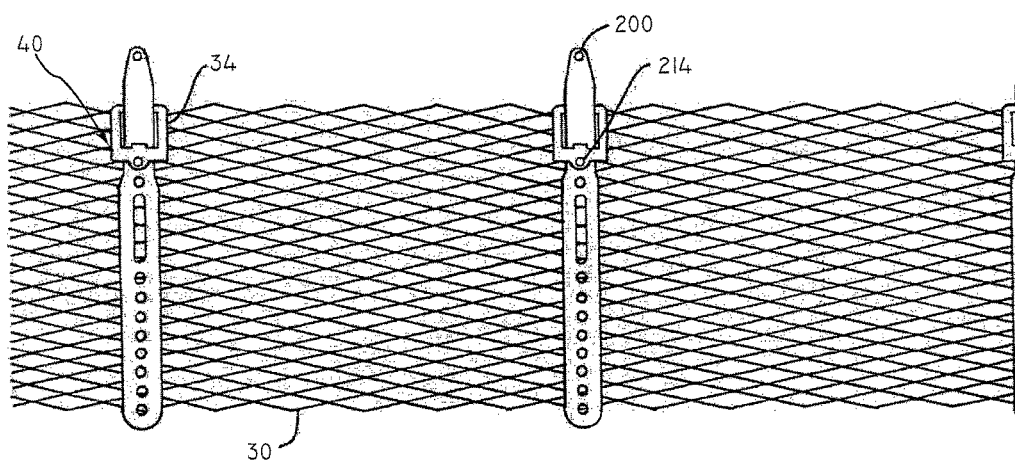


FIG 5B

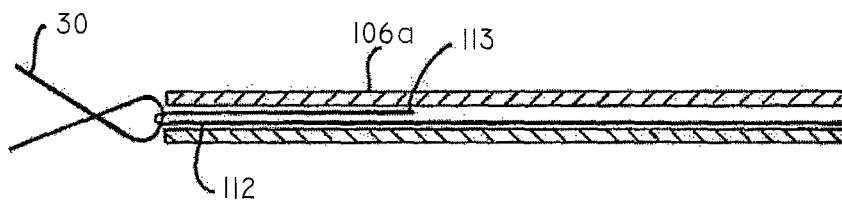


FIG 6

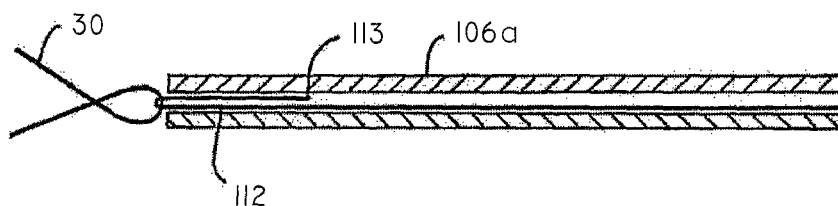


FIG 7

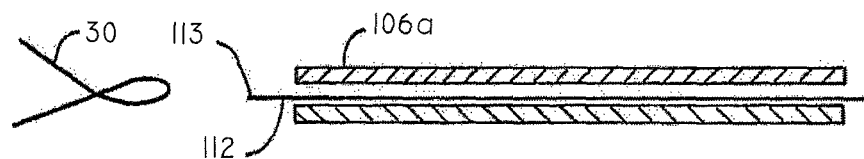


FIG 8

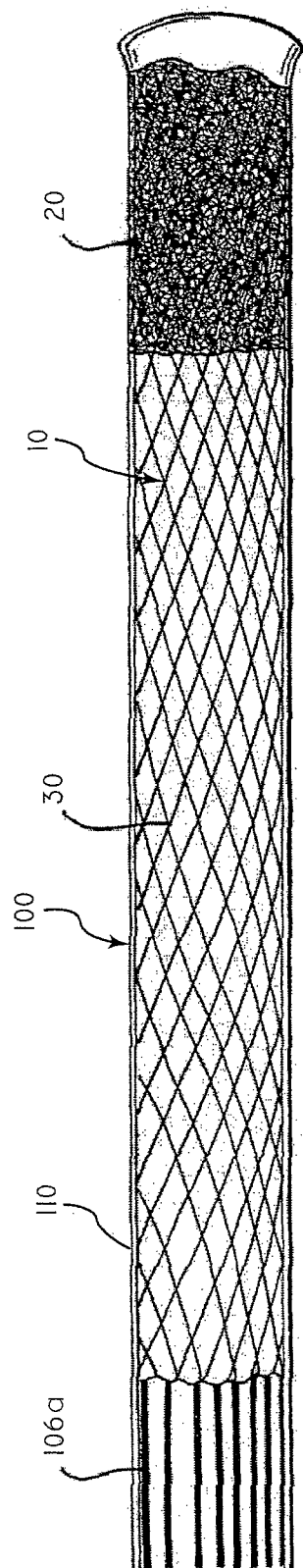


FIG 9

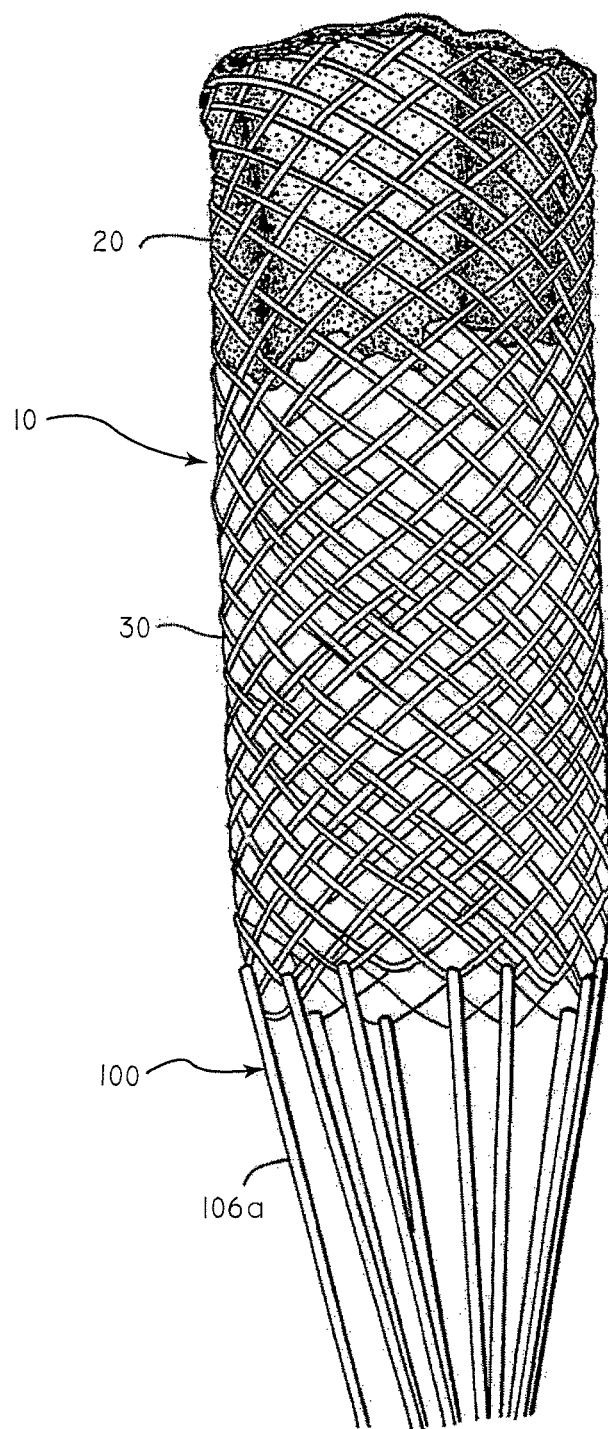


FIG 10

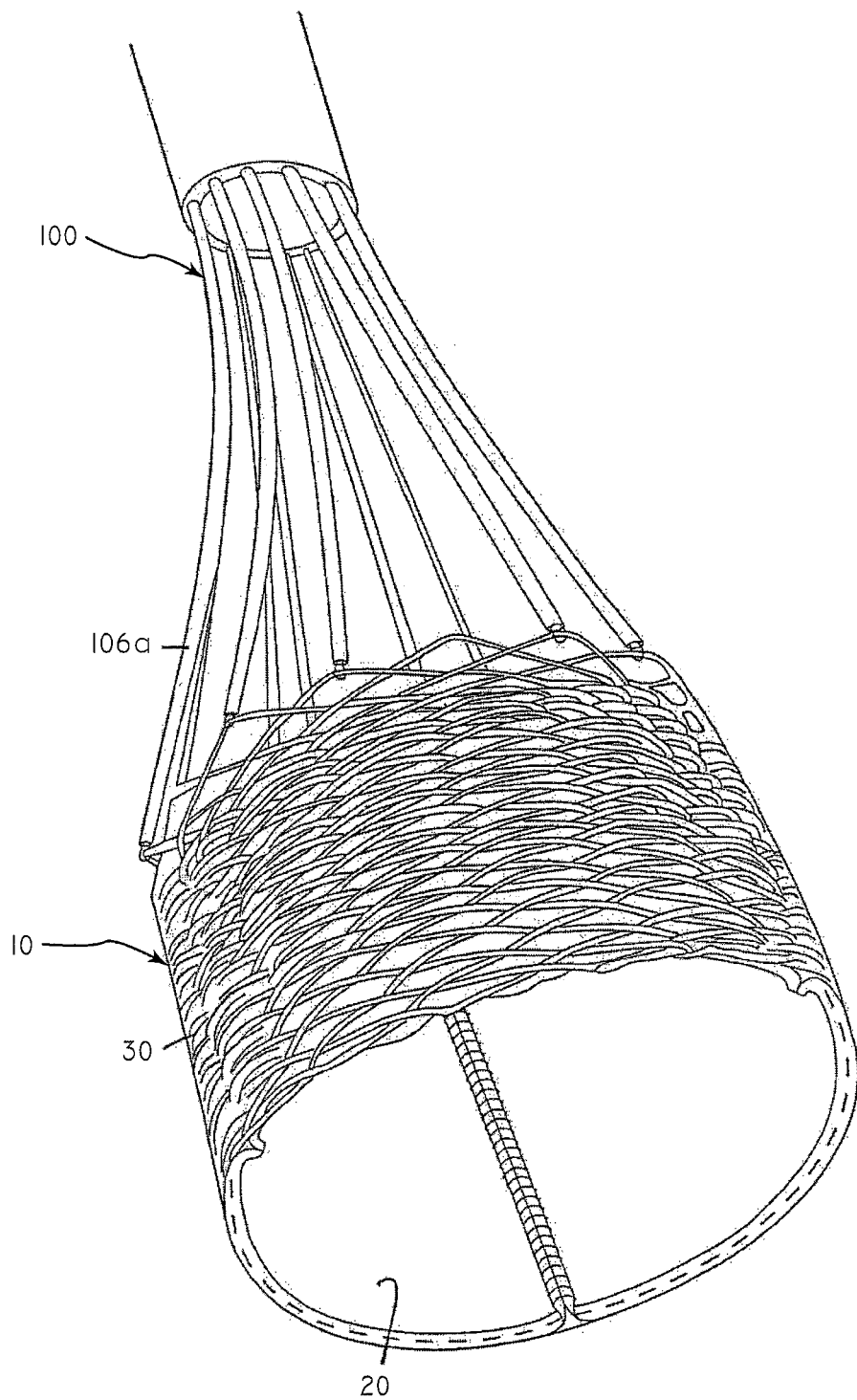


FIG II

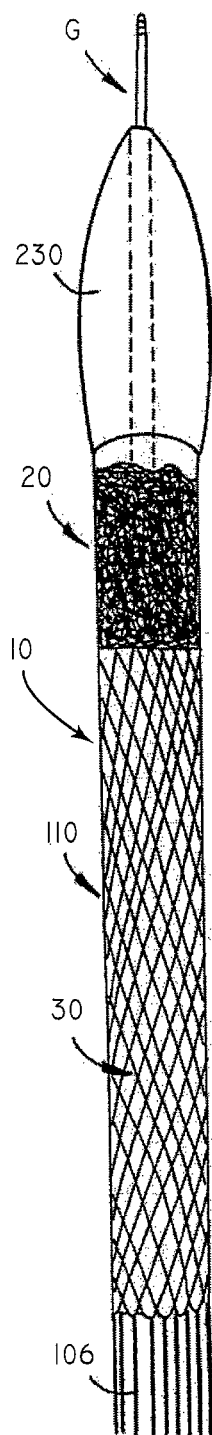


FIG 12

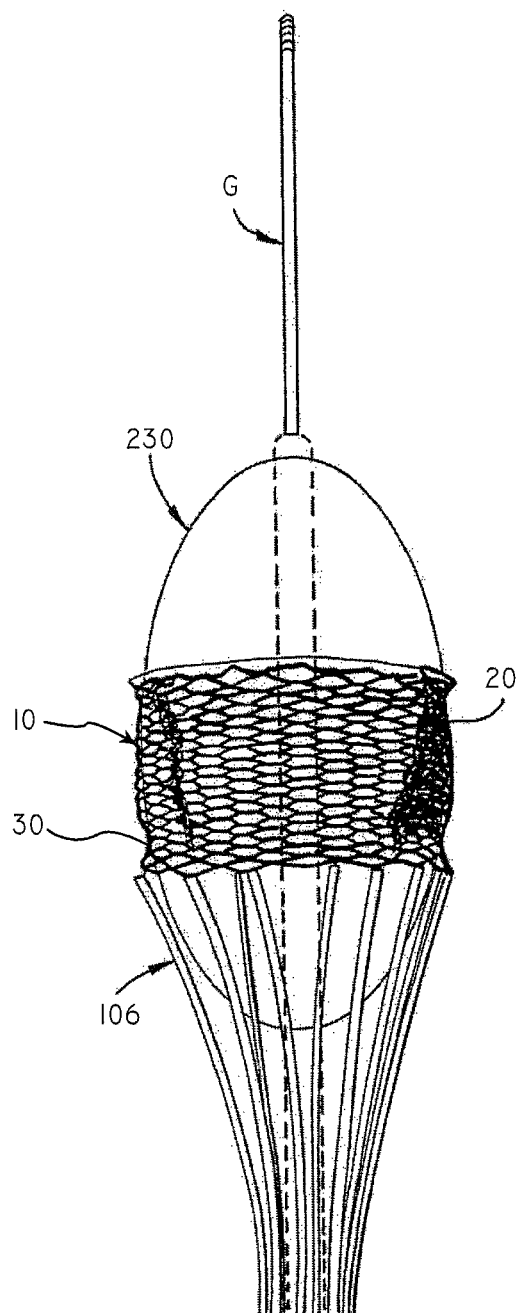


FIG 13

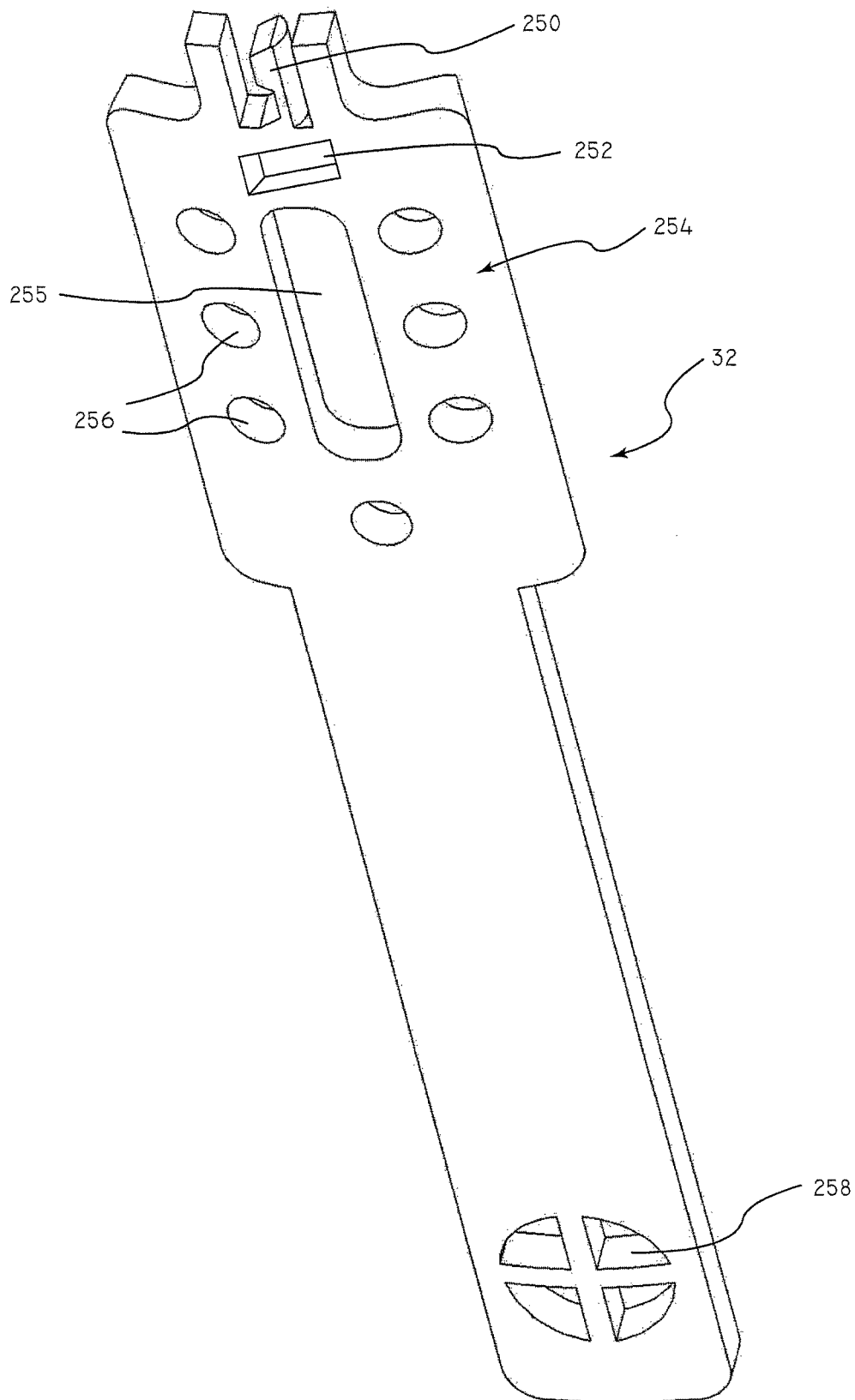
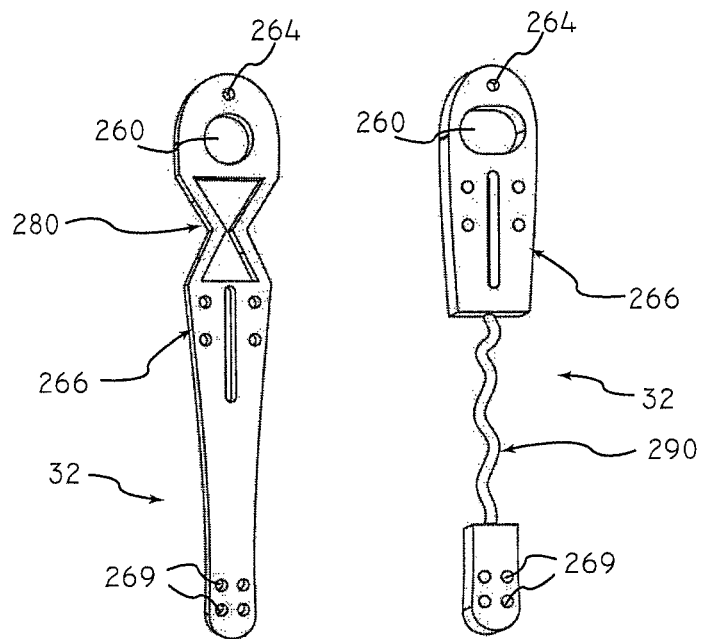
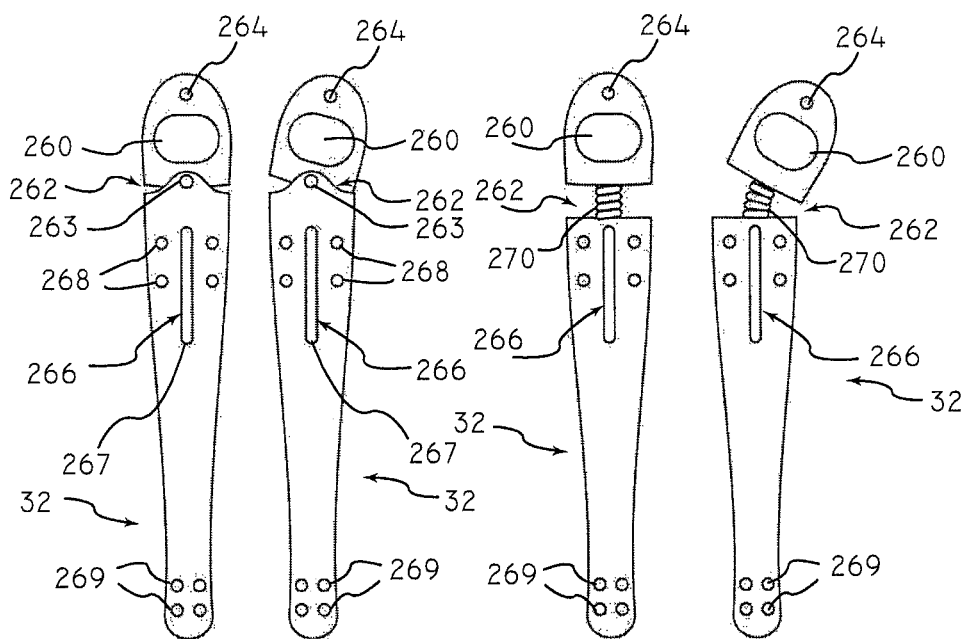
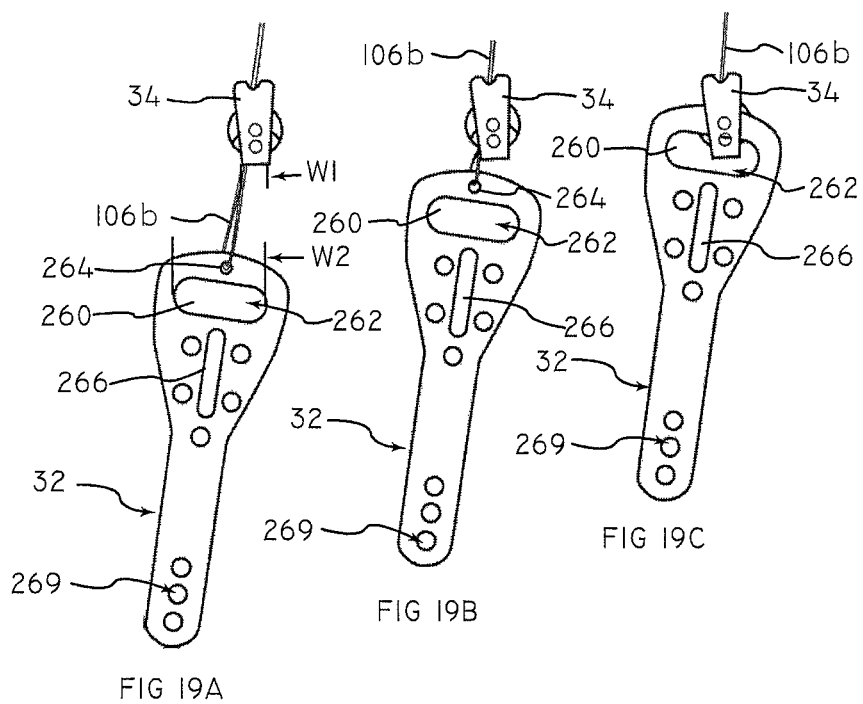
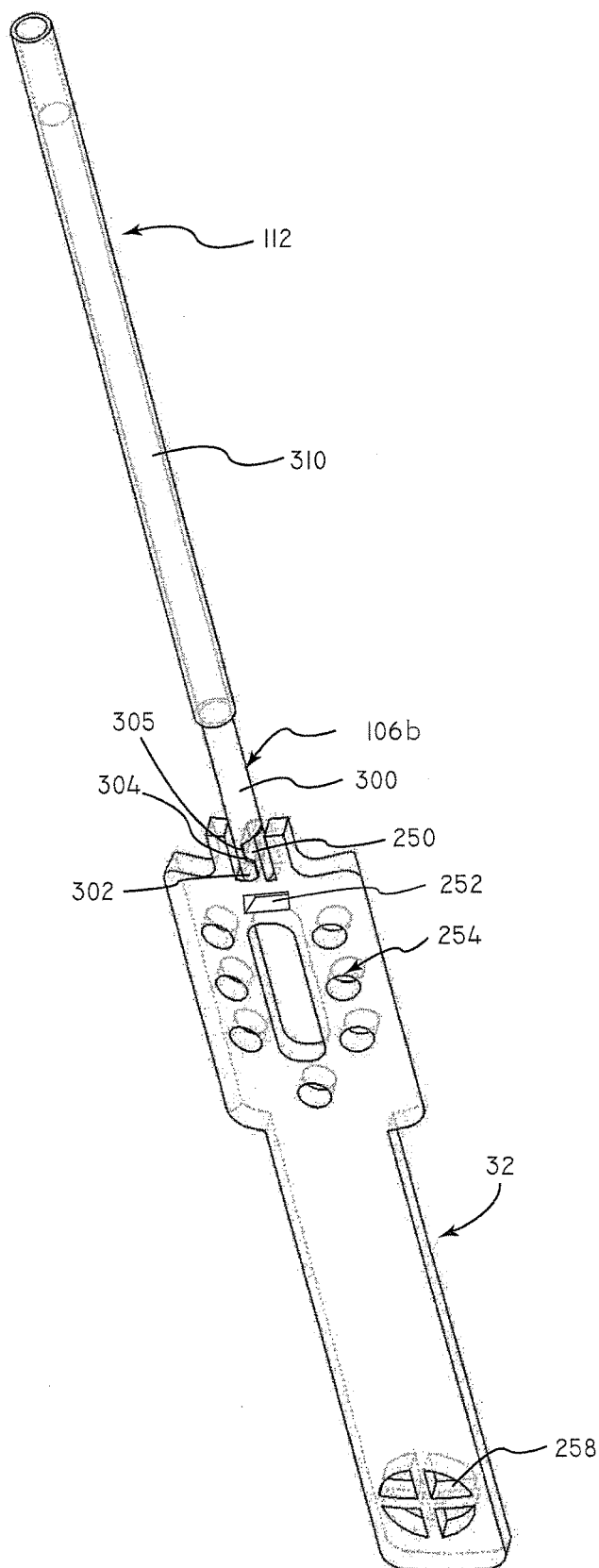
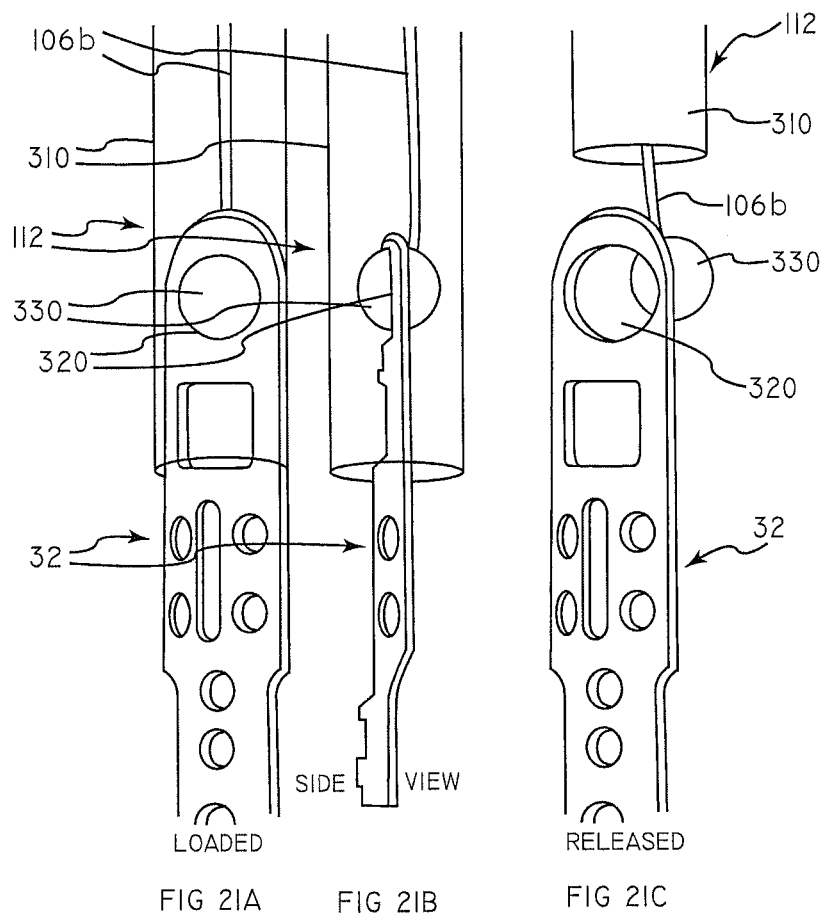


FIG 14









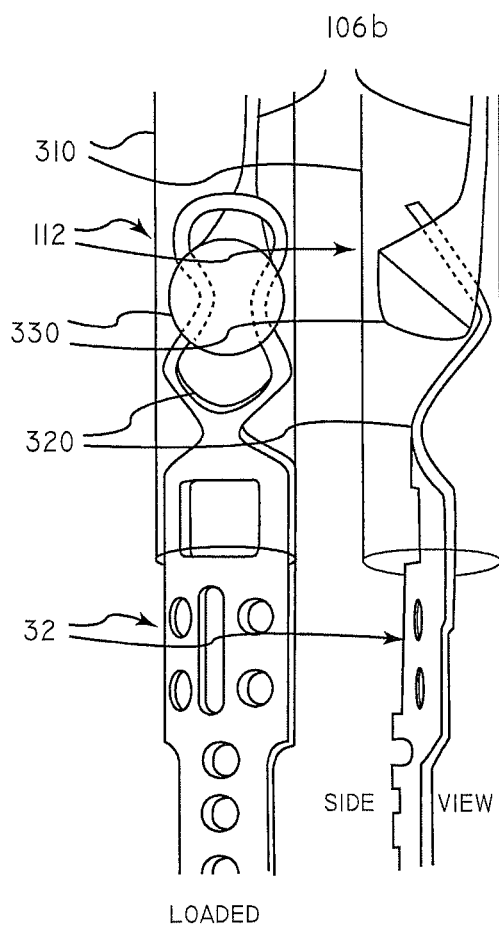


FIG 22A

FIG 22B

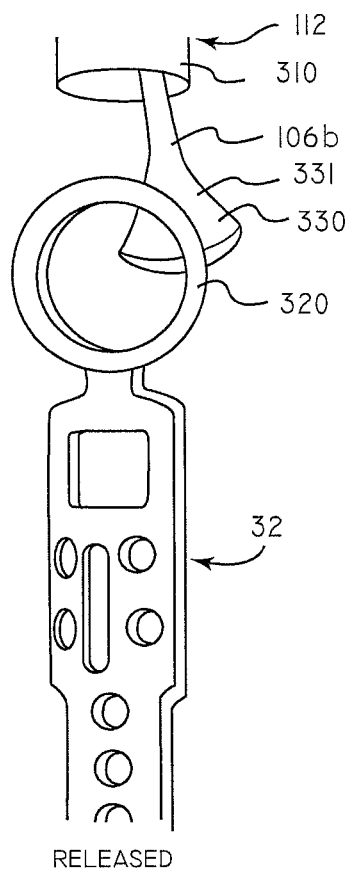
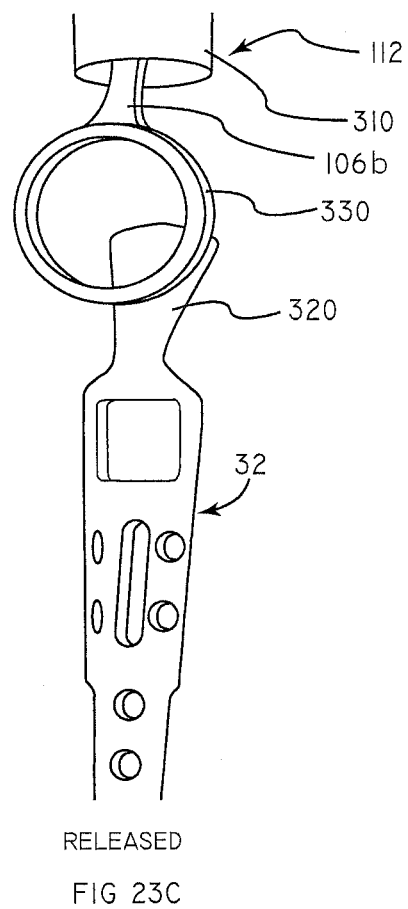
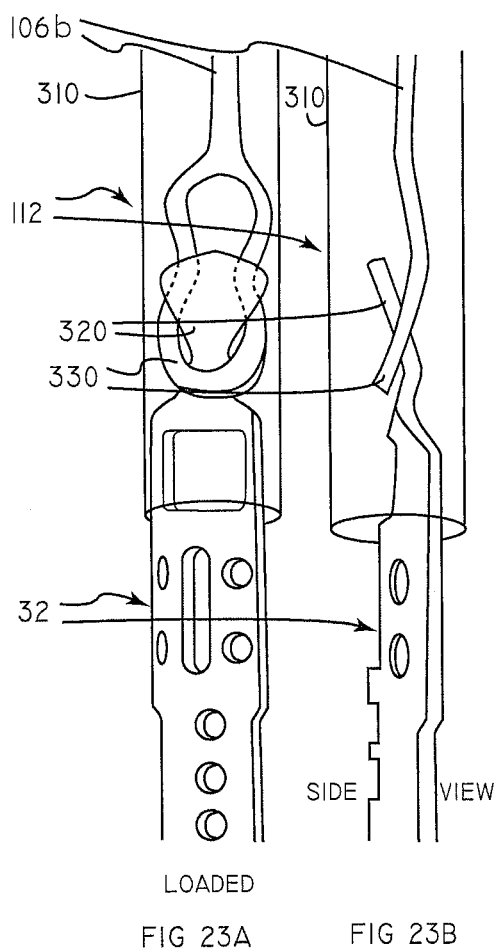


FIG 22C



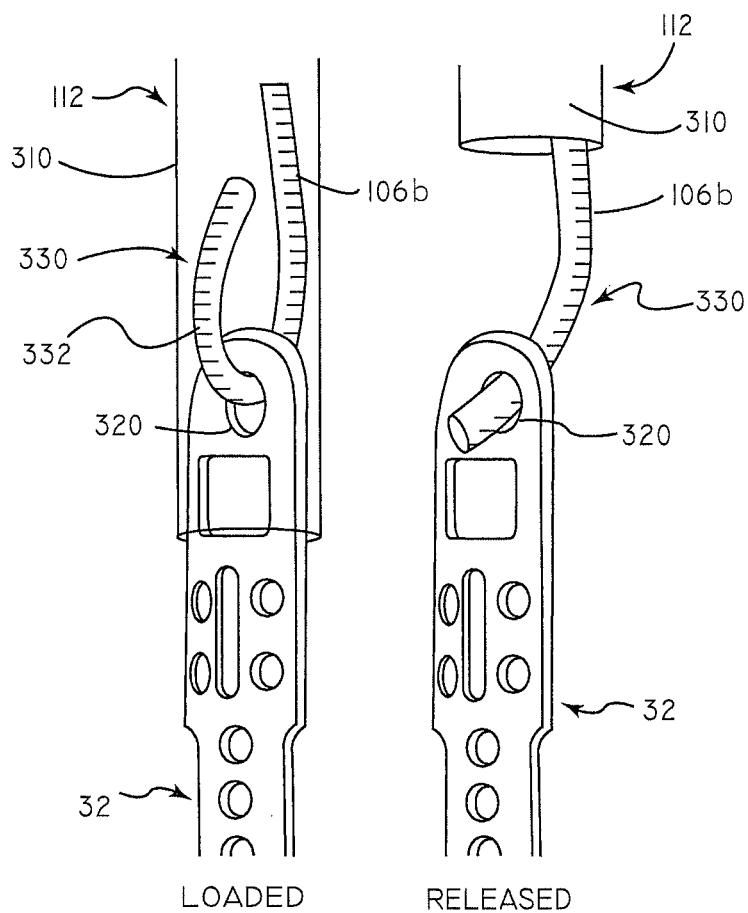


FIG 24A

FIG 24B

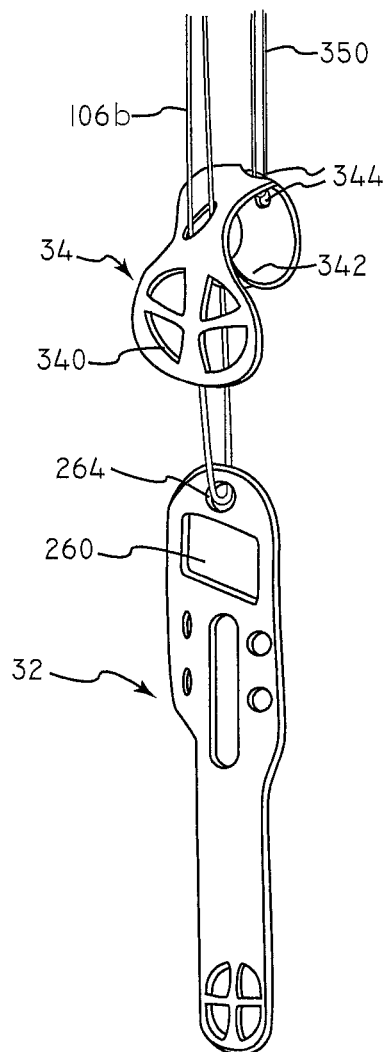


FIG 25

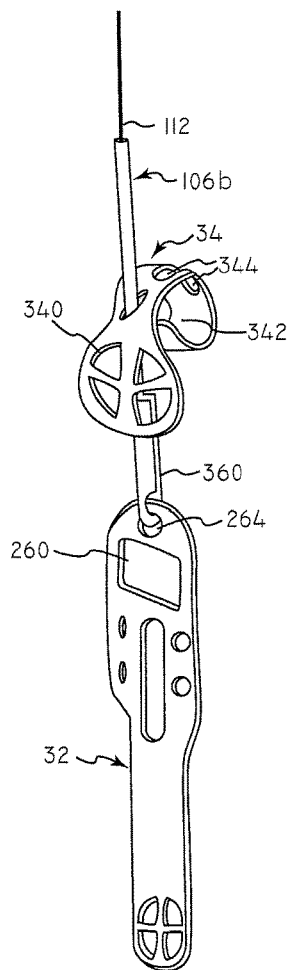


FIG 26A

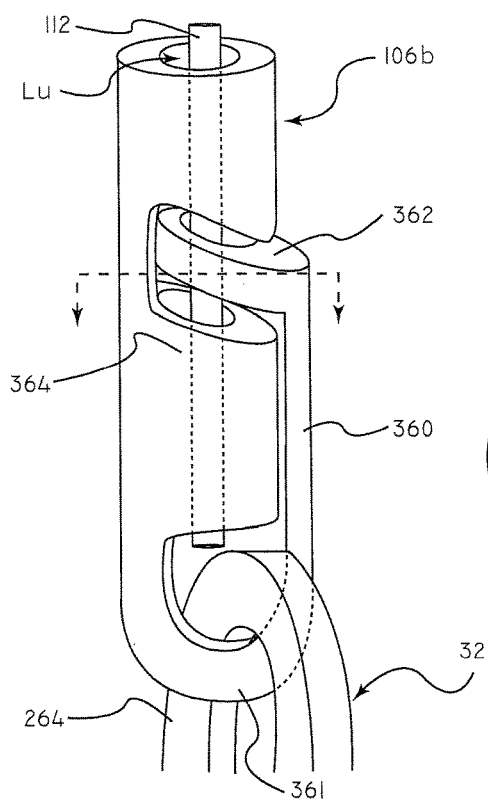


FIG 26B

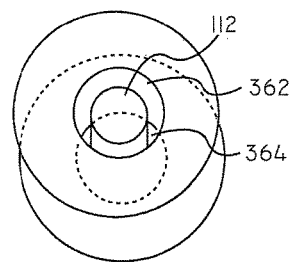


FIG 26C

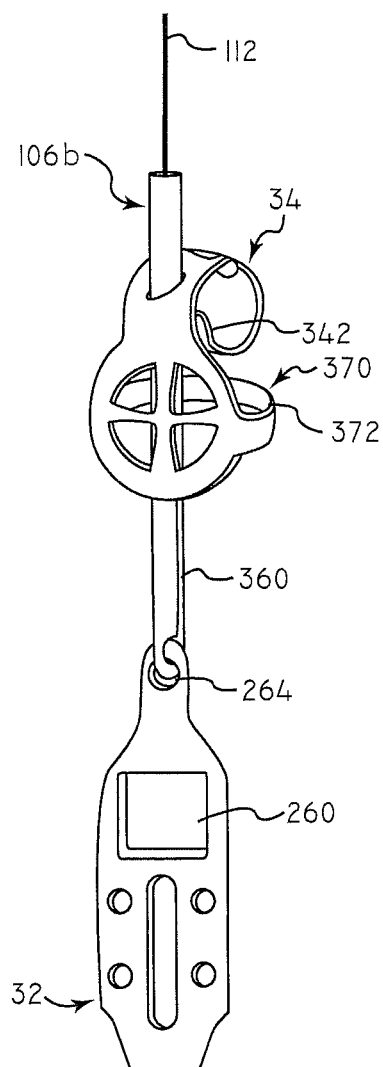
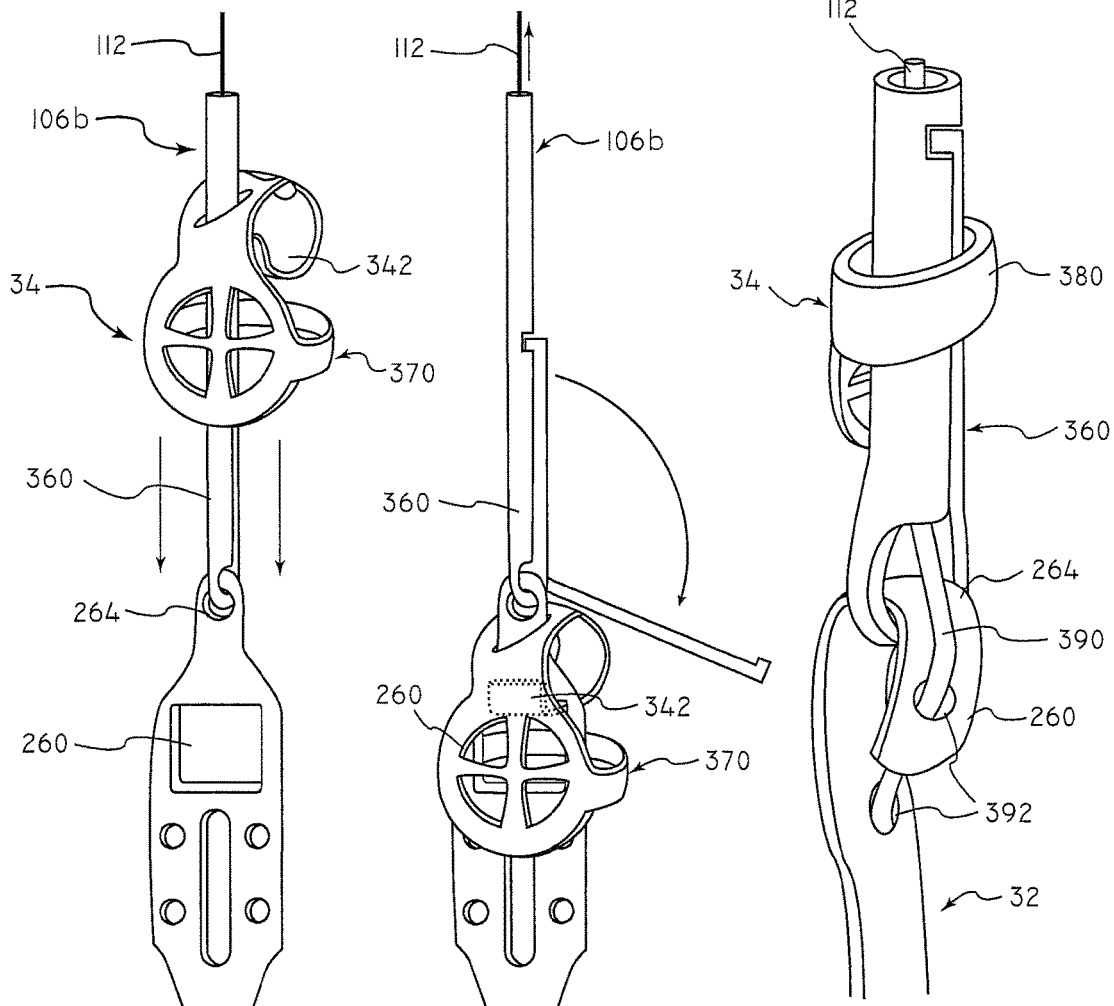


FIG 27



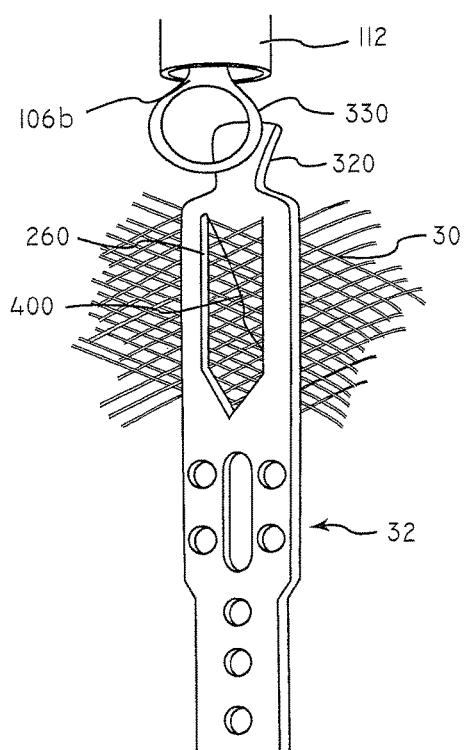


FIG 30A

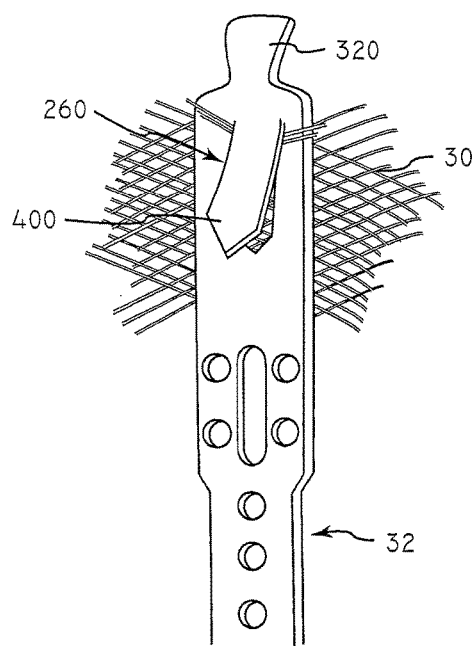


FIG 30B

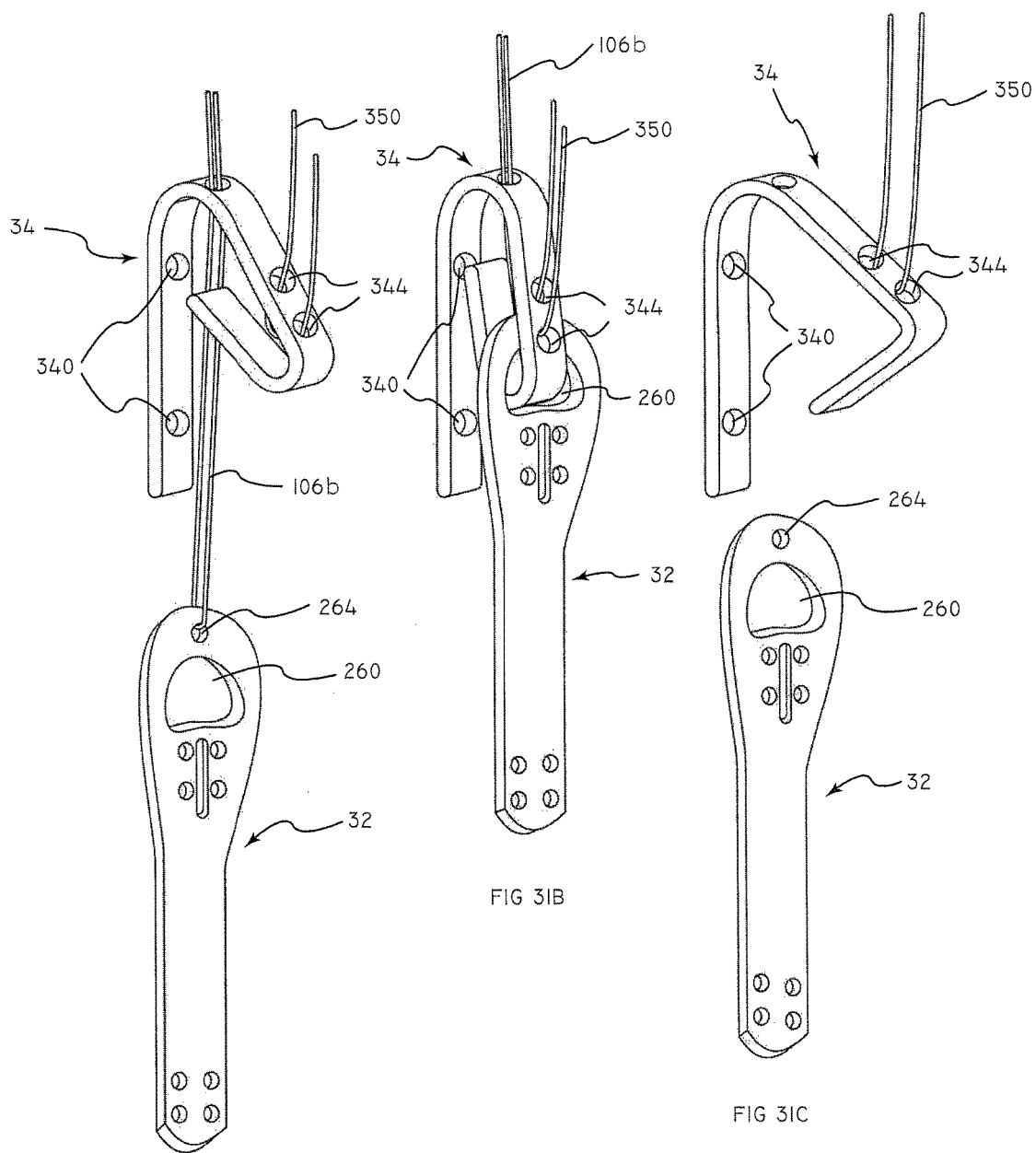


FIG 31A

FIG 31B

FIG 31C

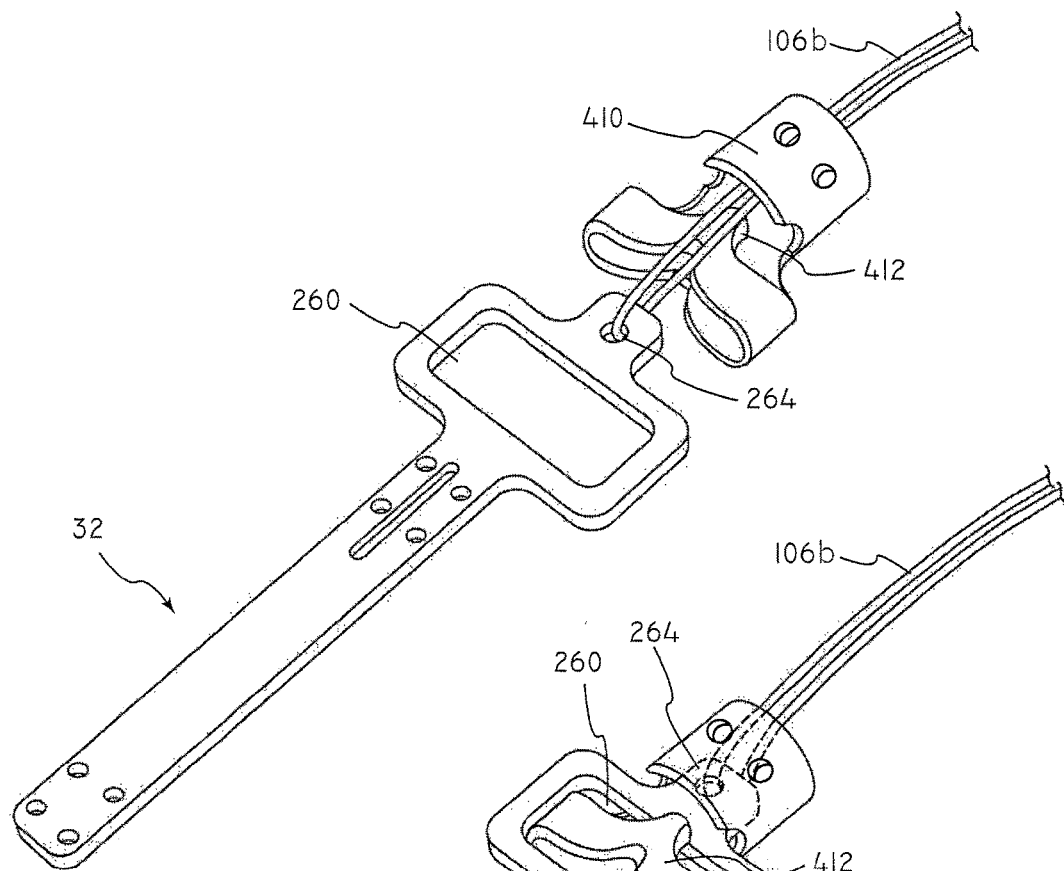


FIG 32A

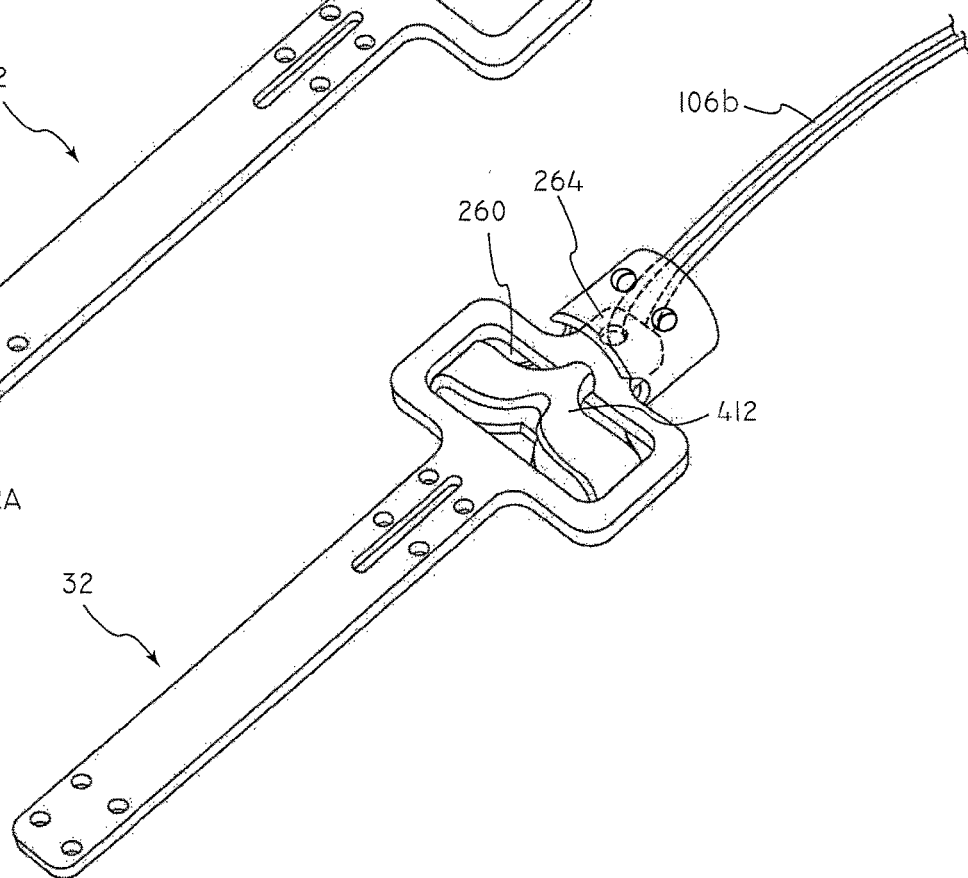


FIG 32B

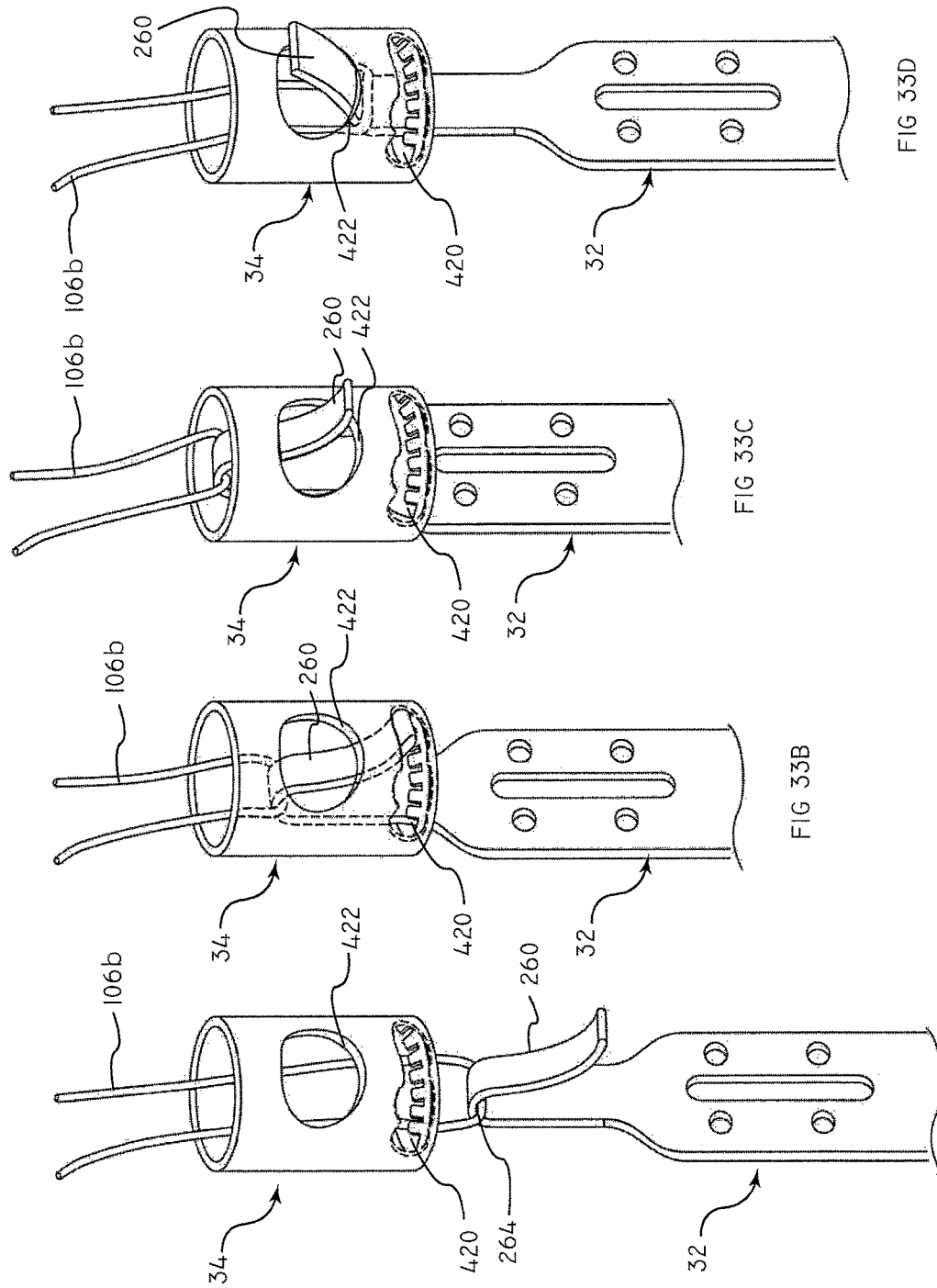
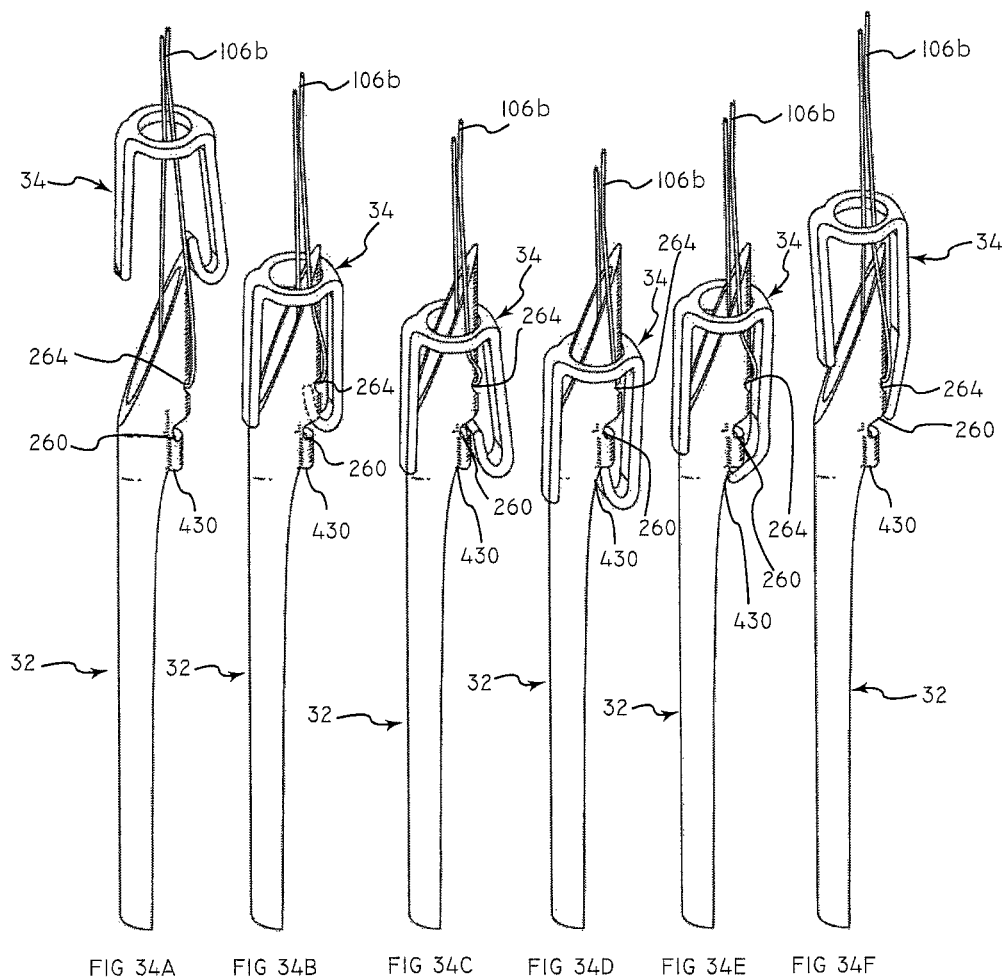


FIG 33D

FIG 33C

FIG 33B

FIG 33A



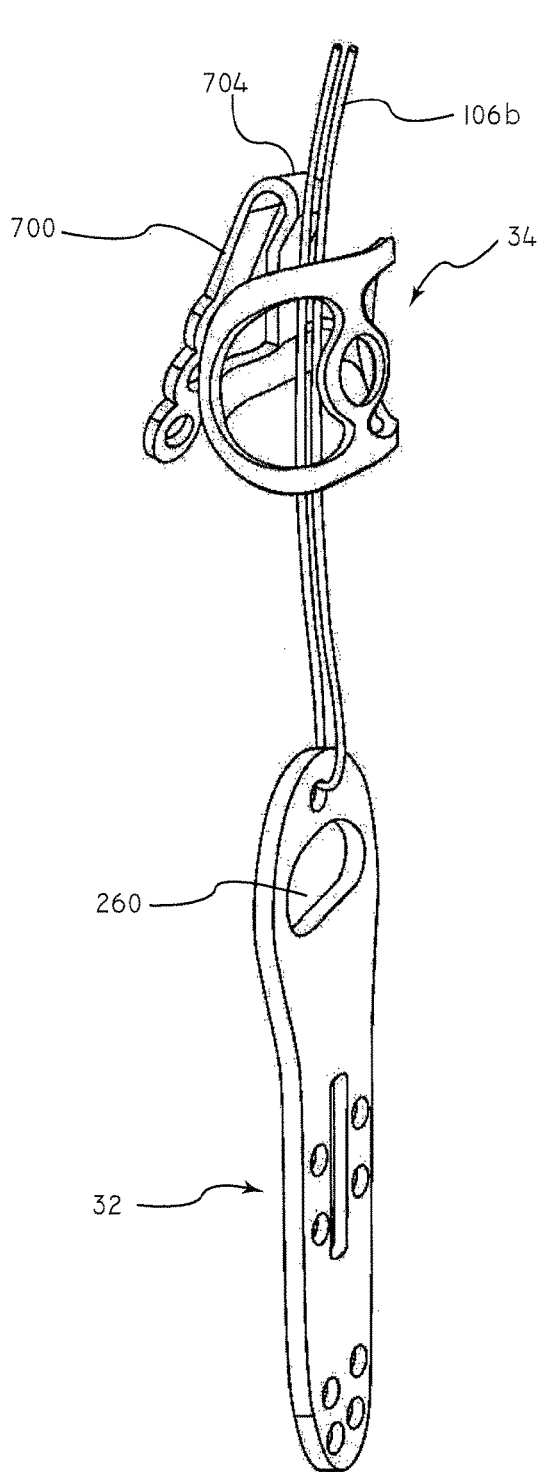


FIG 35A

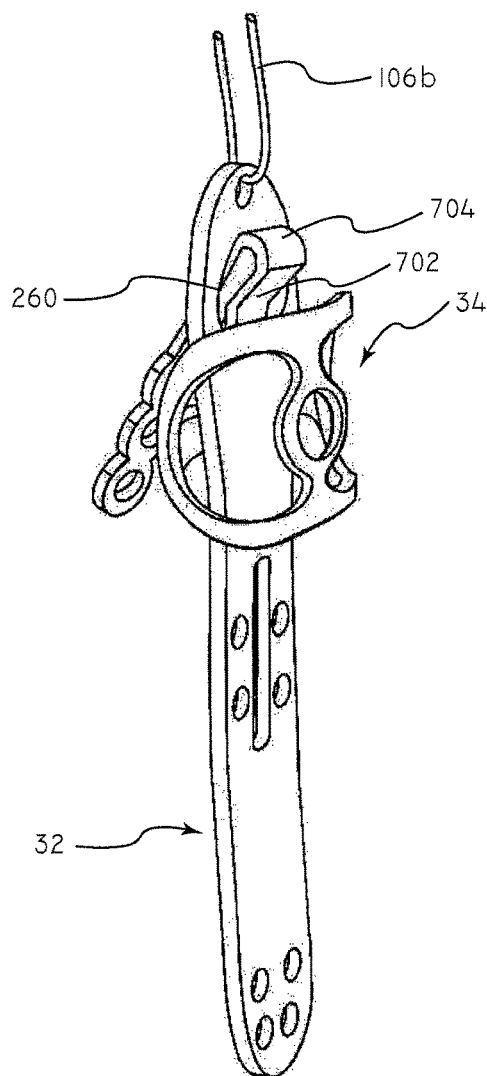


FIG 35B

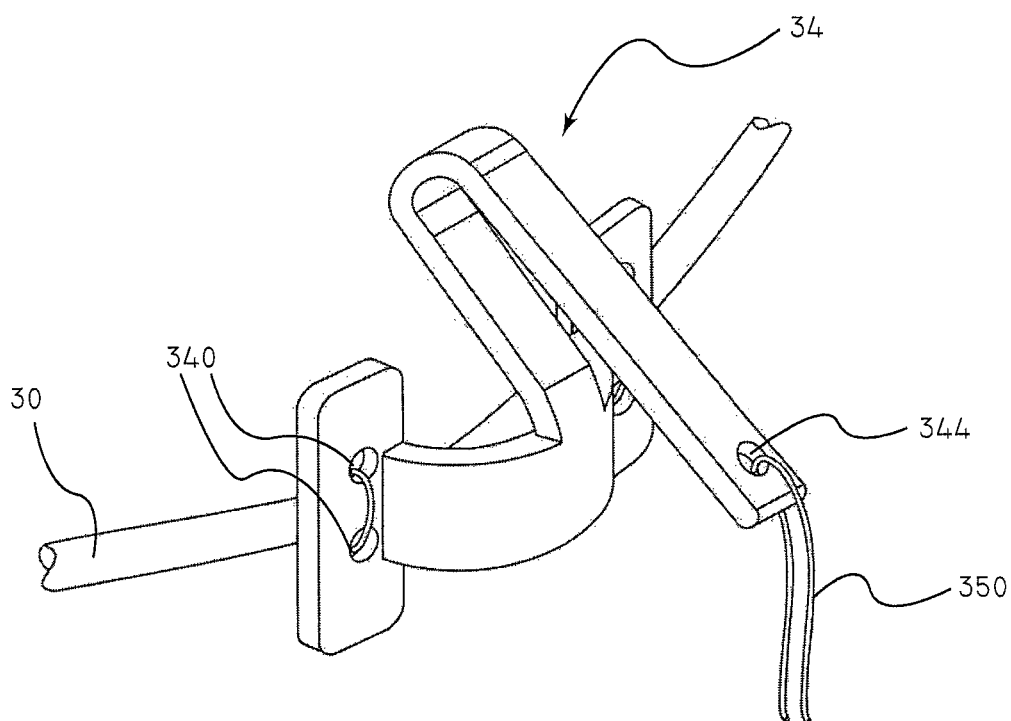


FIG 36

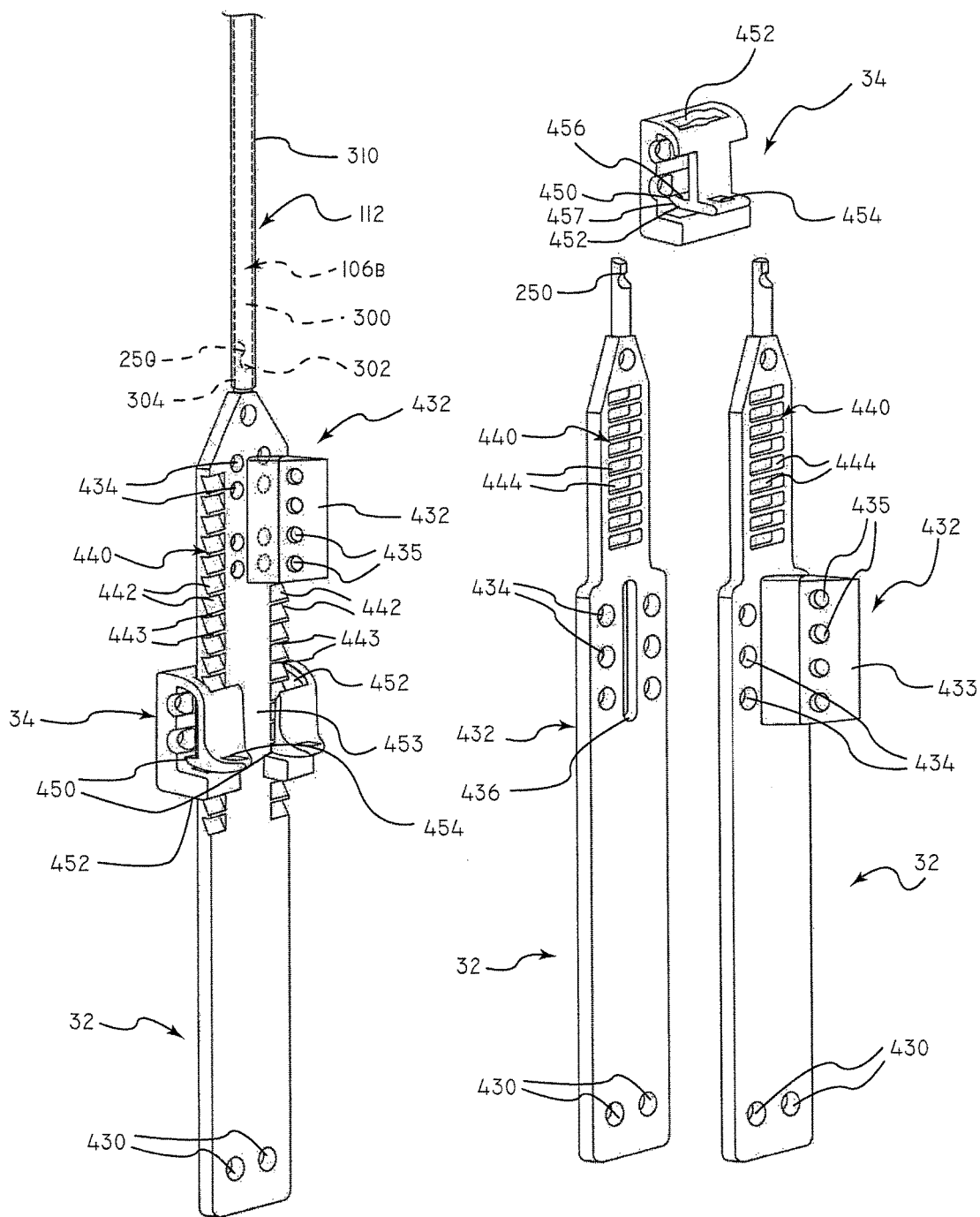


FIG 37

FIG 38A

FIG 38B

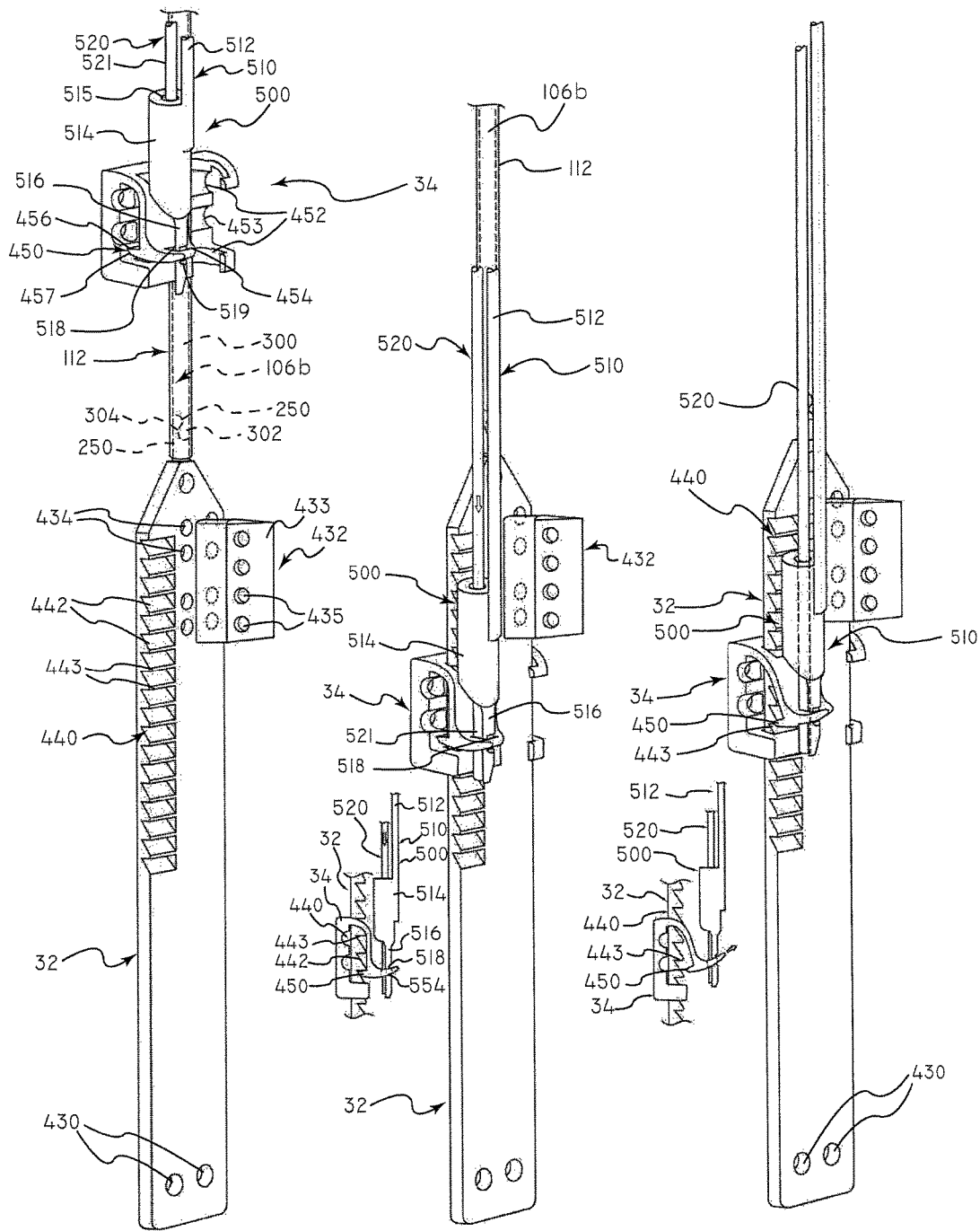


FIG 39A

FIG 39B

FIG 39C

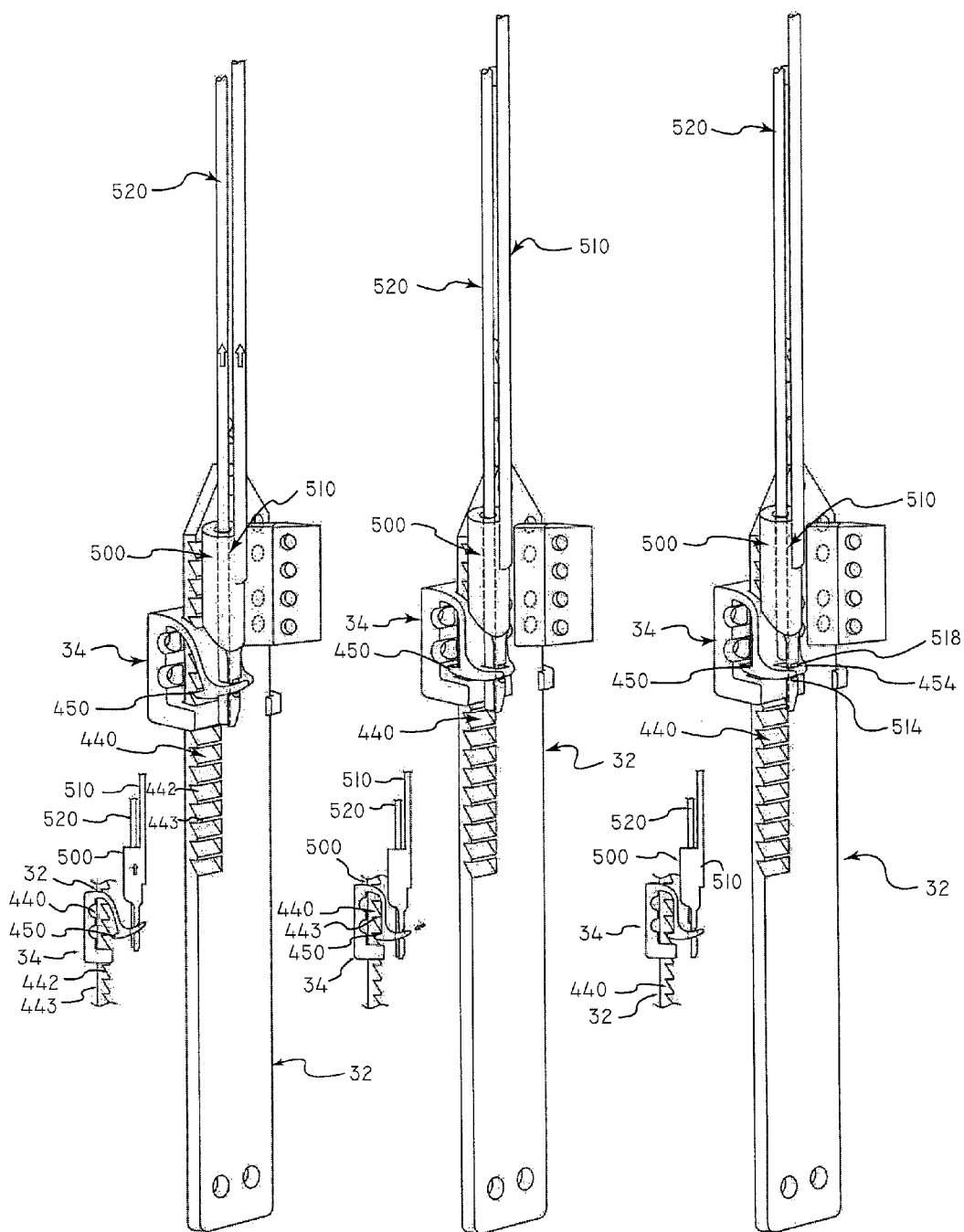


FIG 39D

FIG 39E

FIG 39F

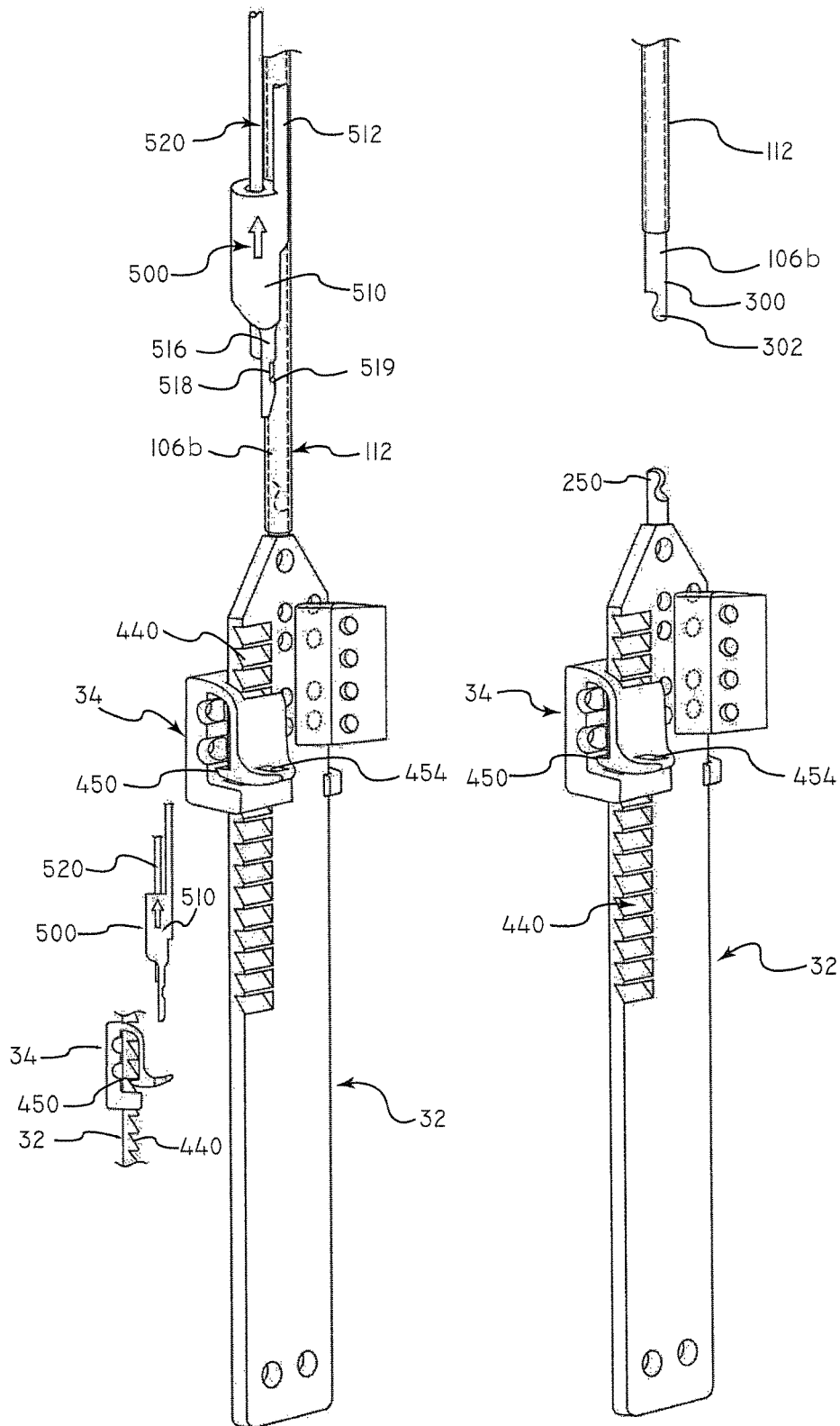
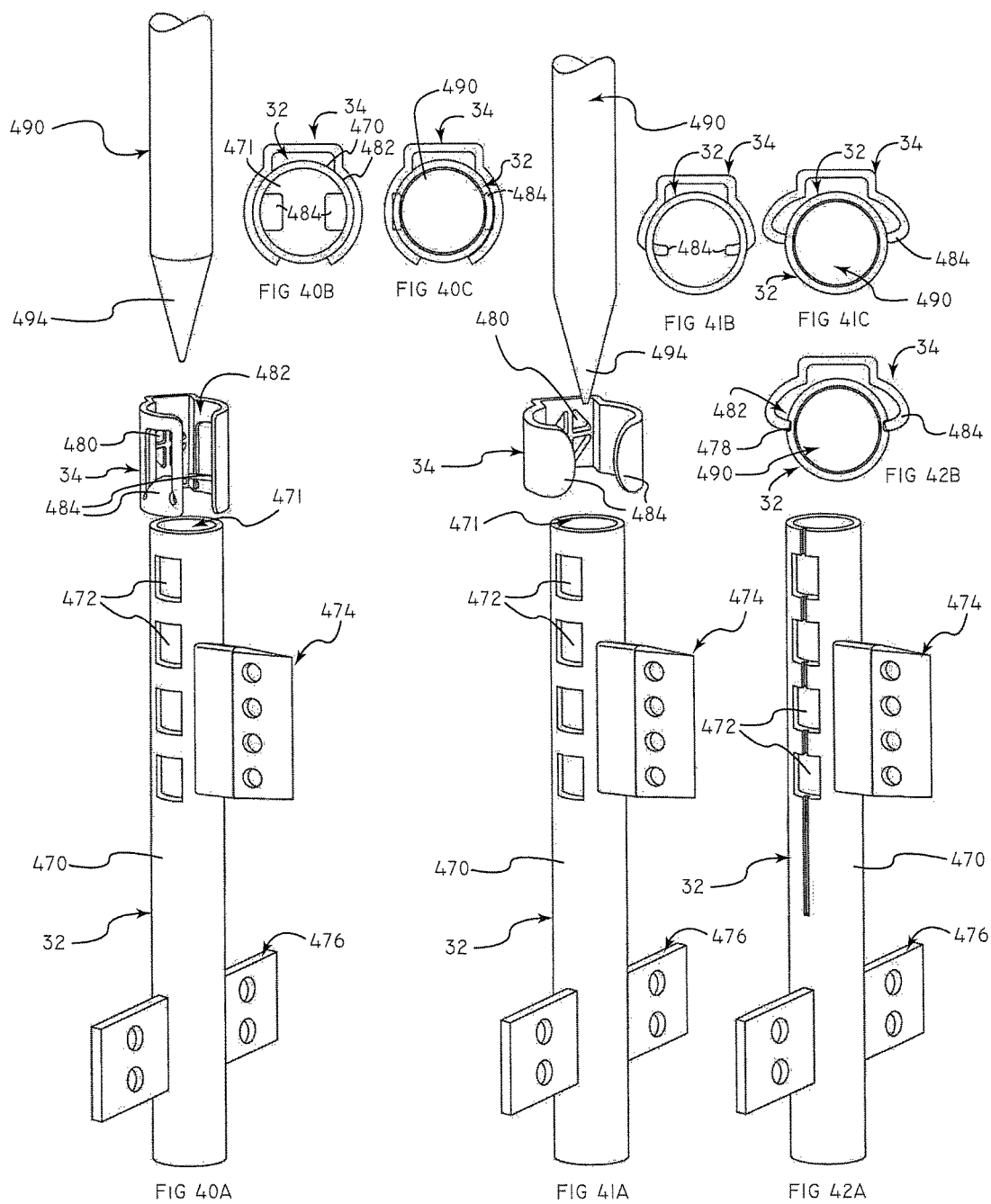


FIG 39G

FIG 39H



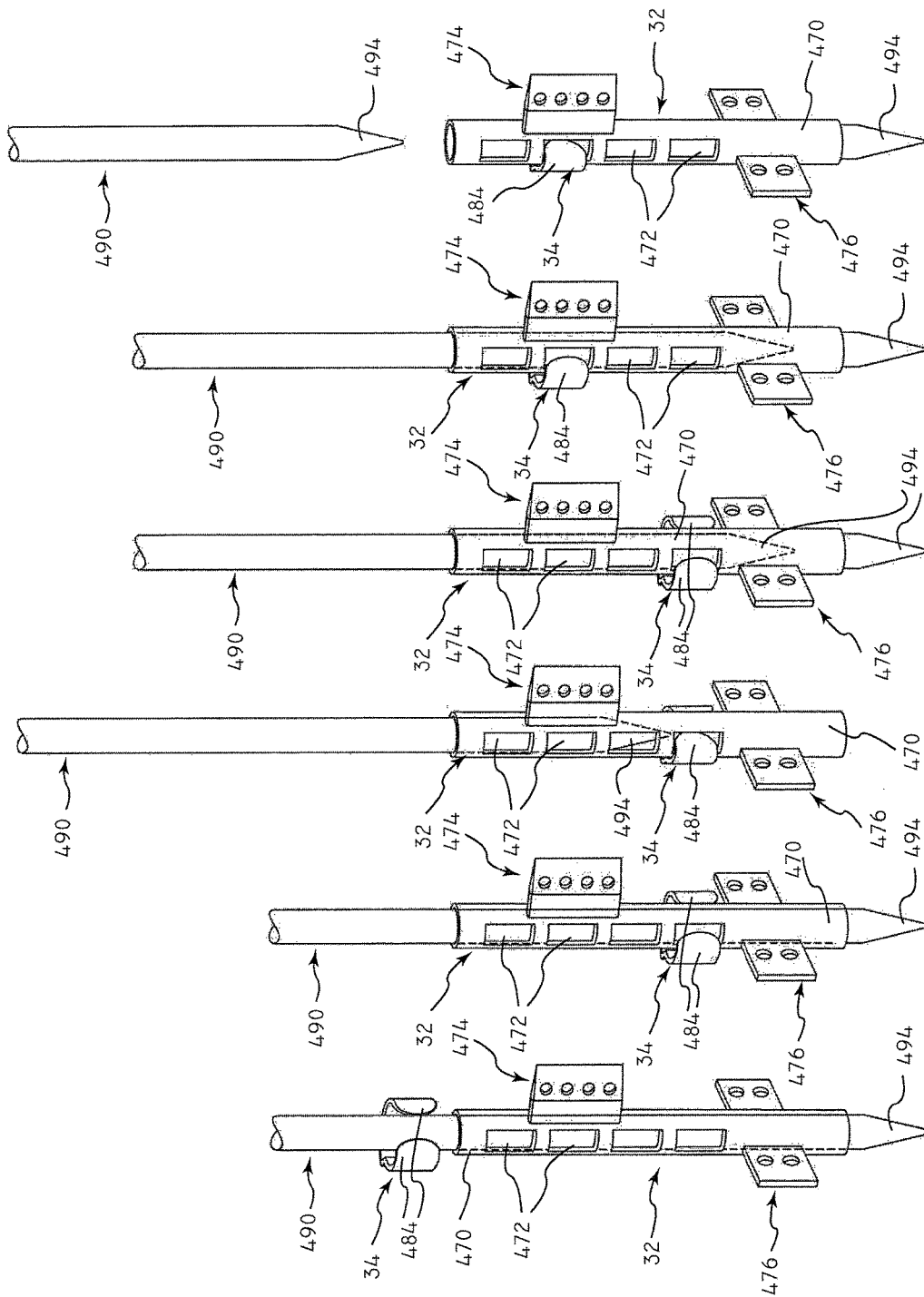


FIG 43F

FIG 43E

FIG 43D

FIG 43C

FIG 43B

FIG 43A

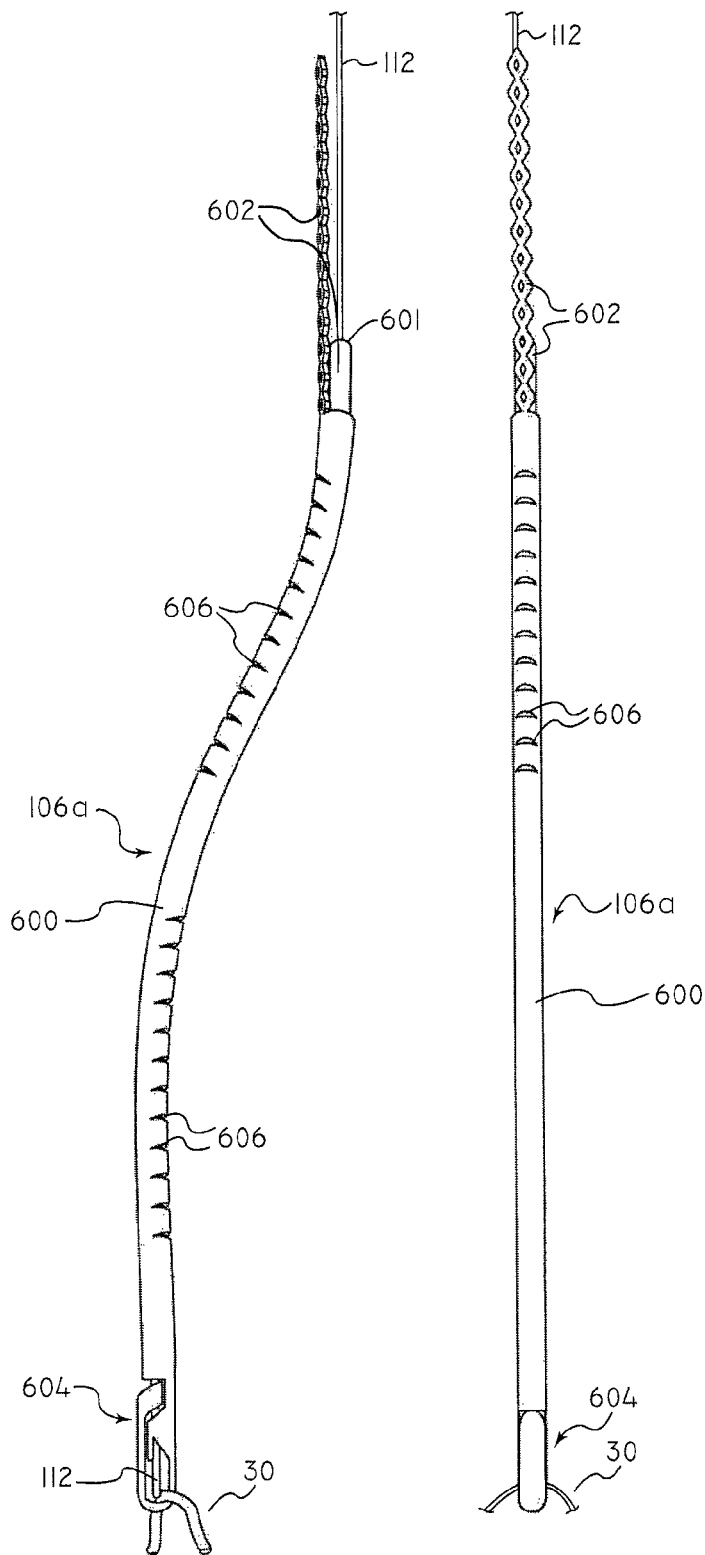
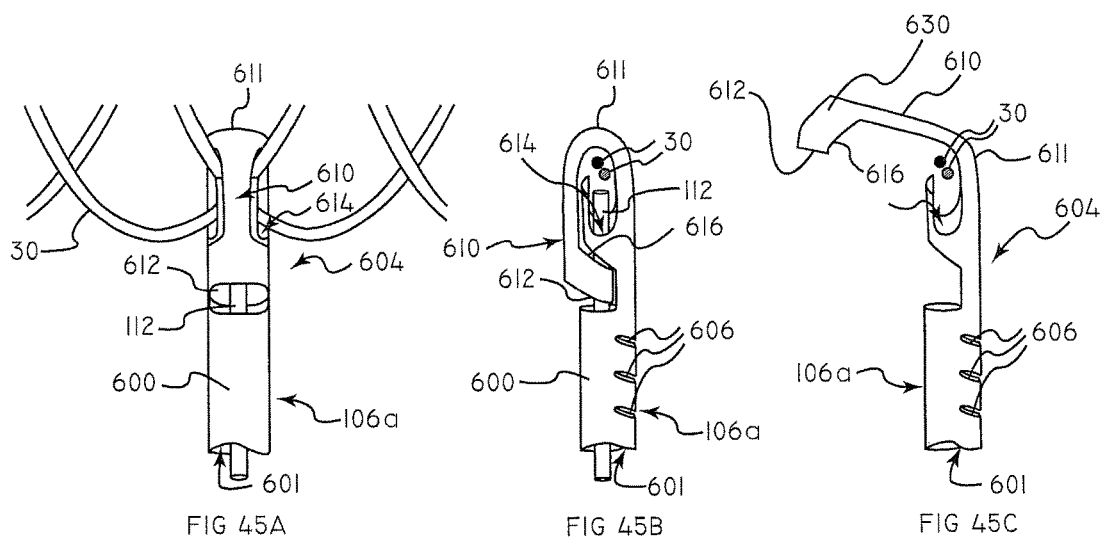
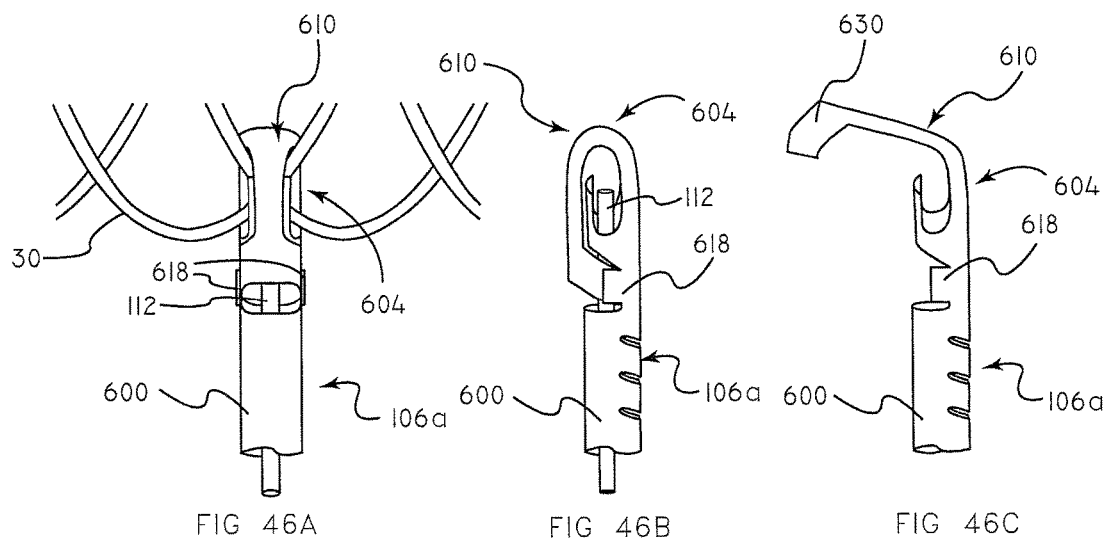
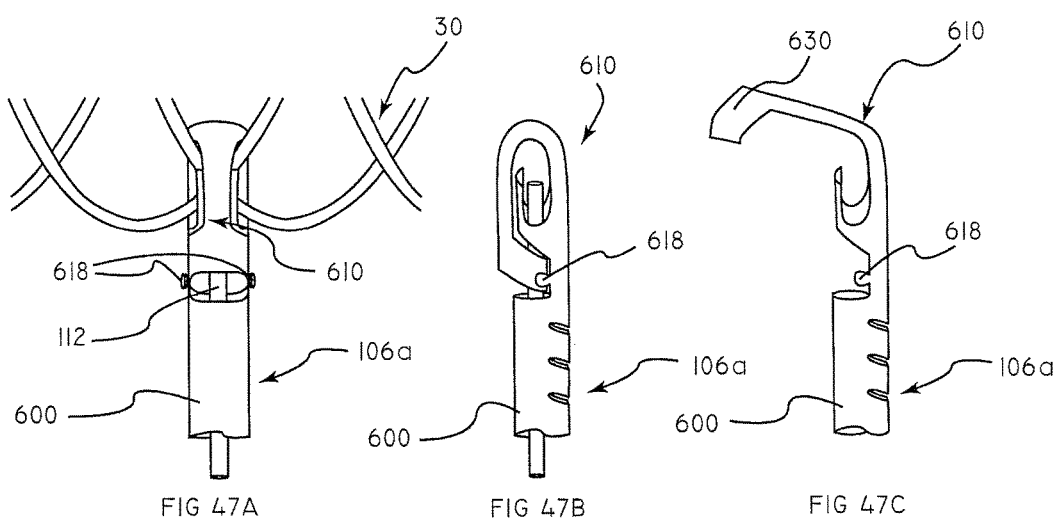


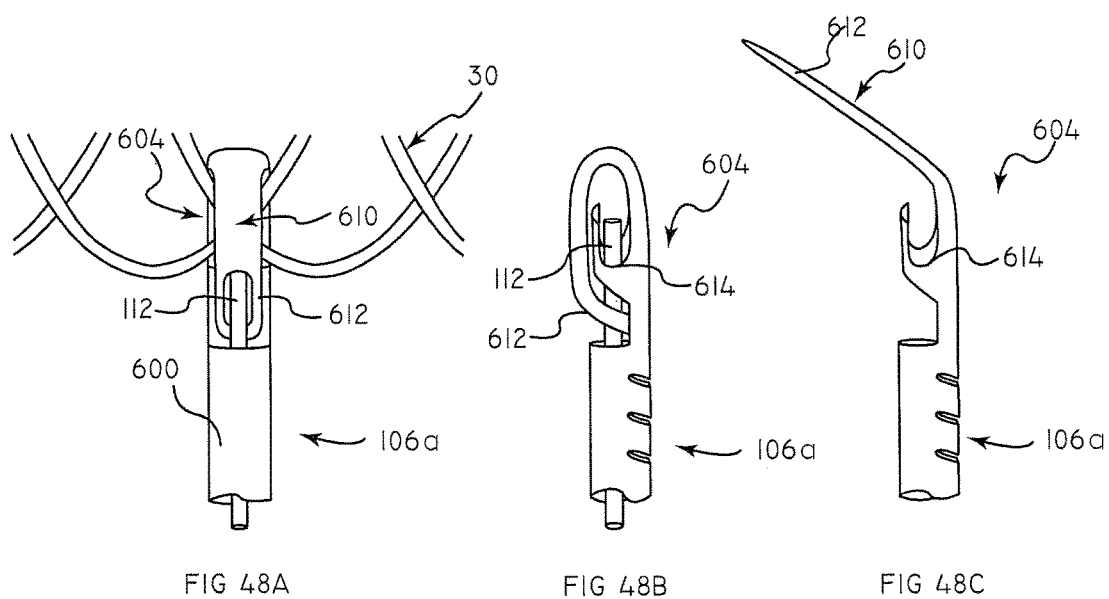
FIG 44A

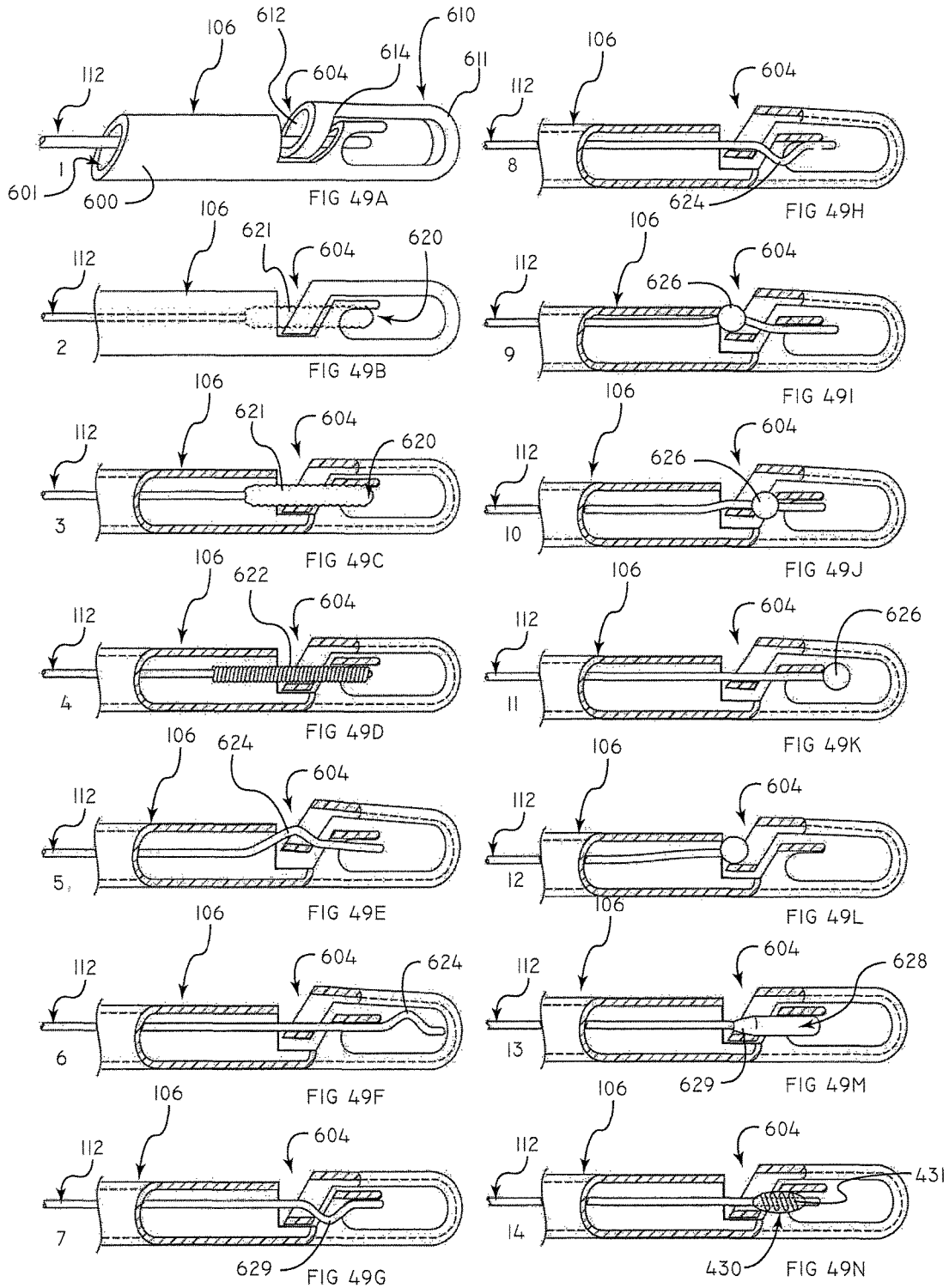
FIG 44B

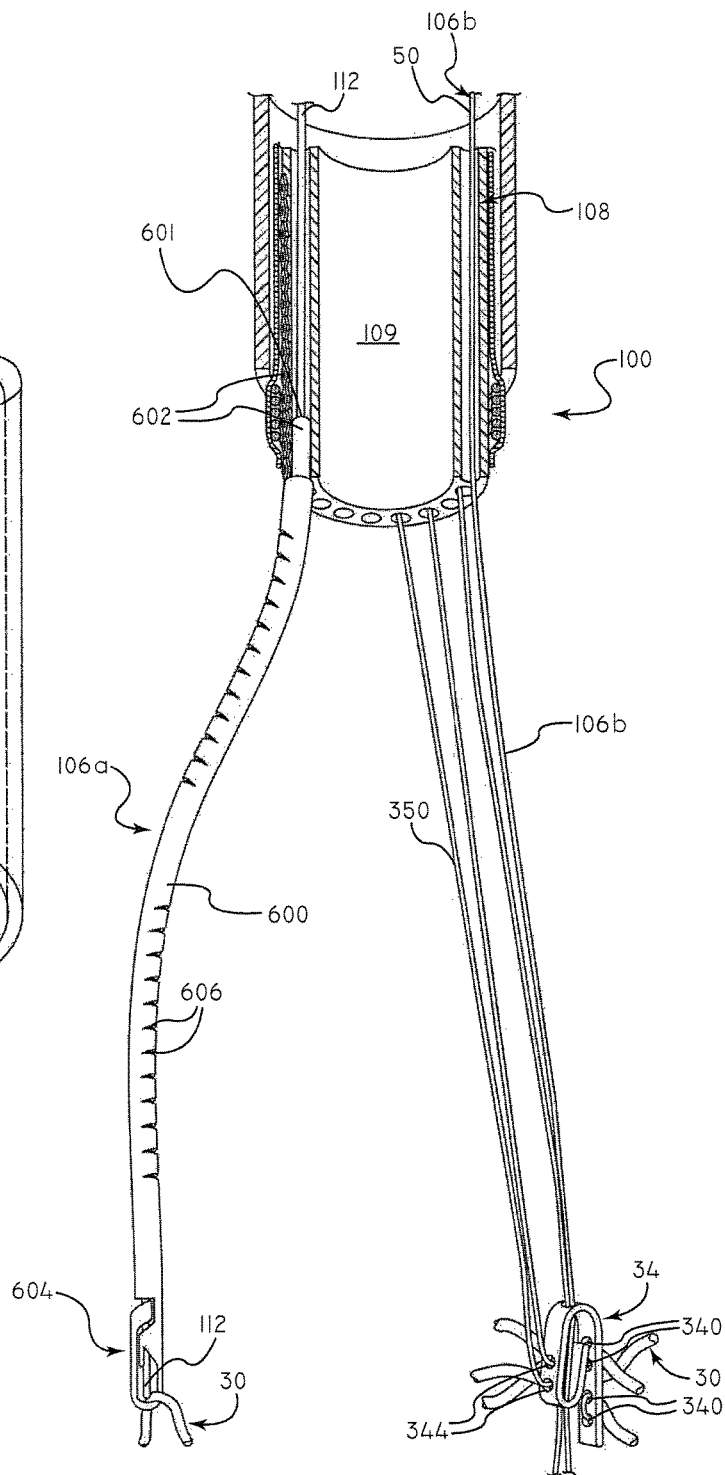
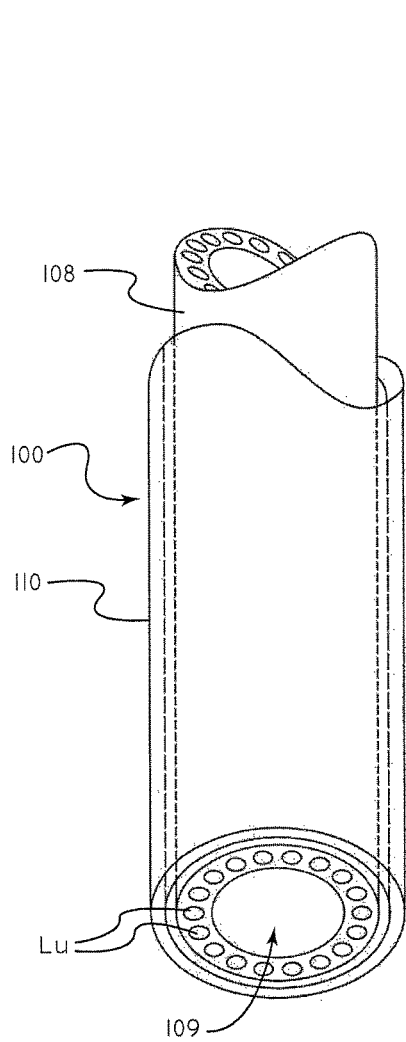












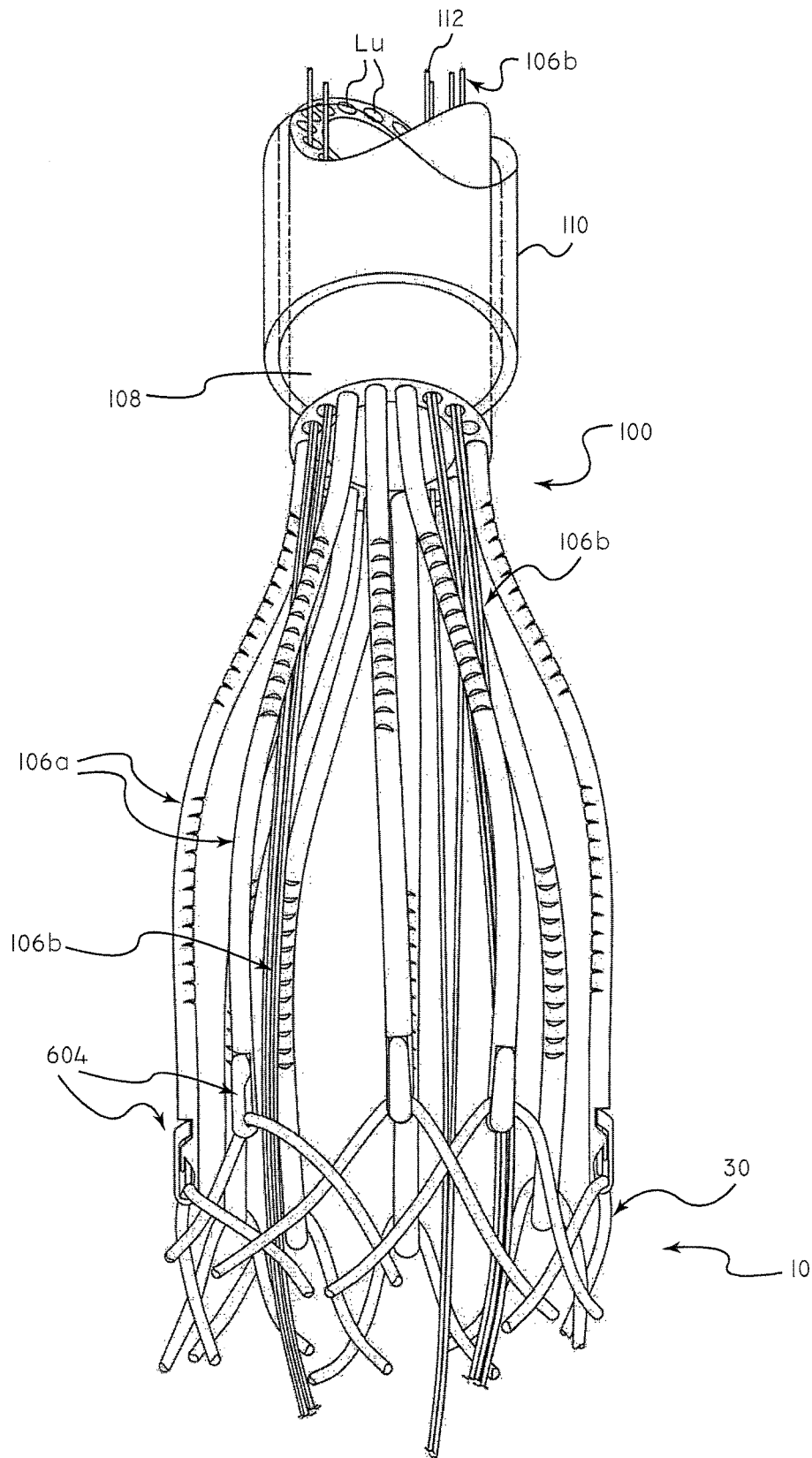


FIG 51A

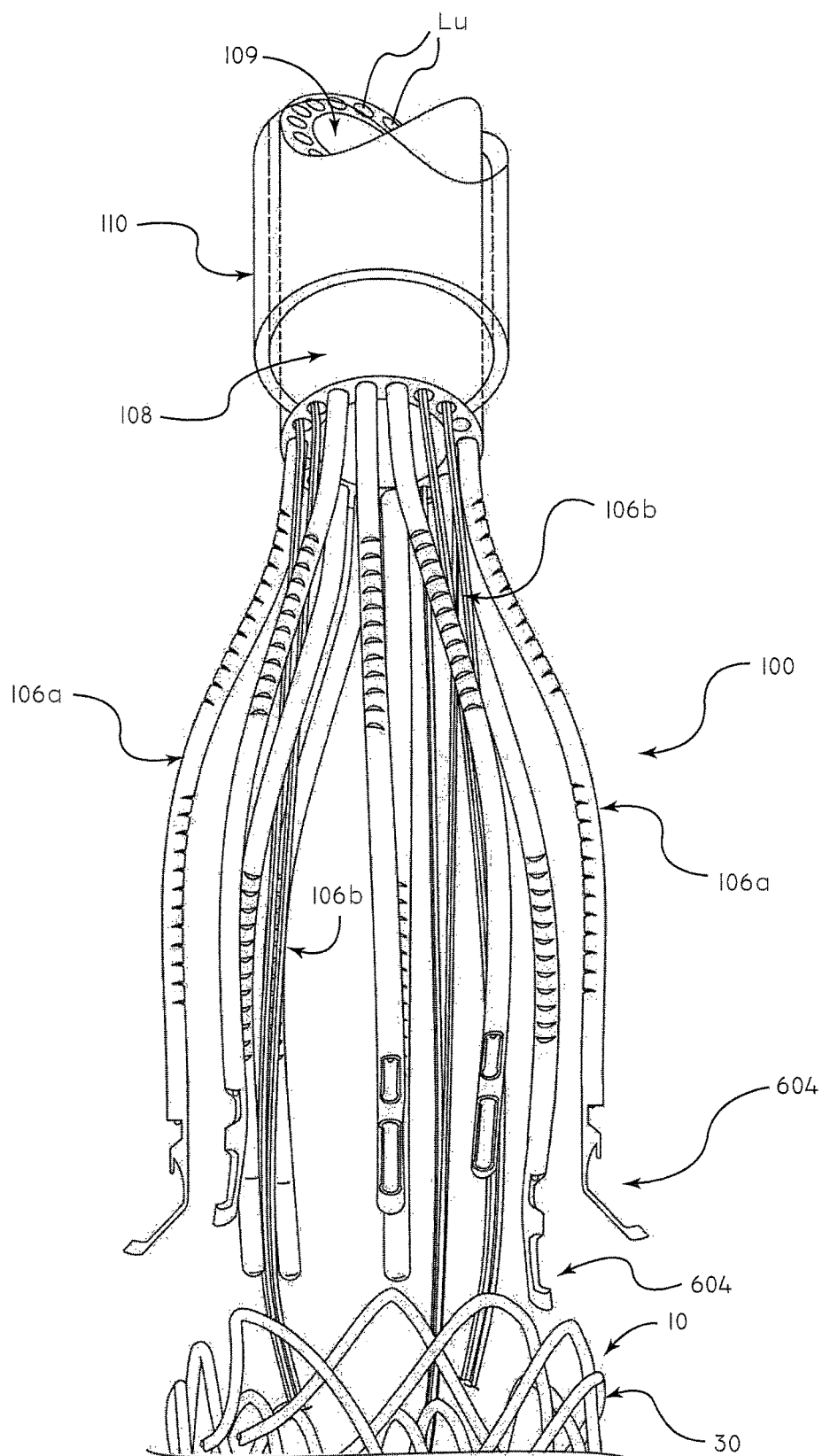


FIG 51B

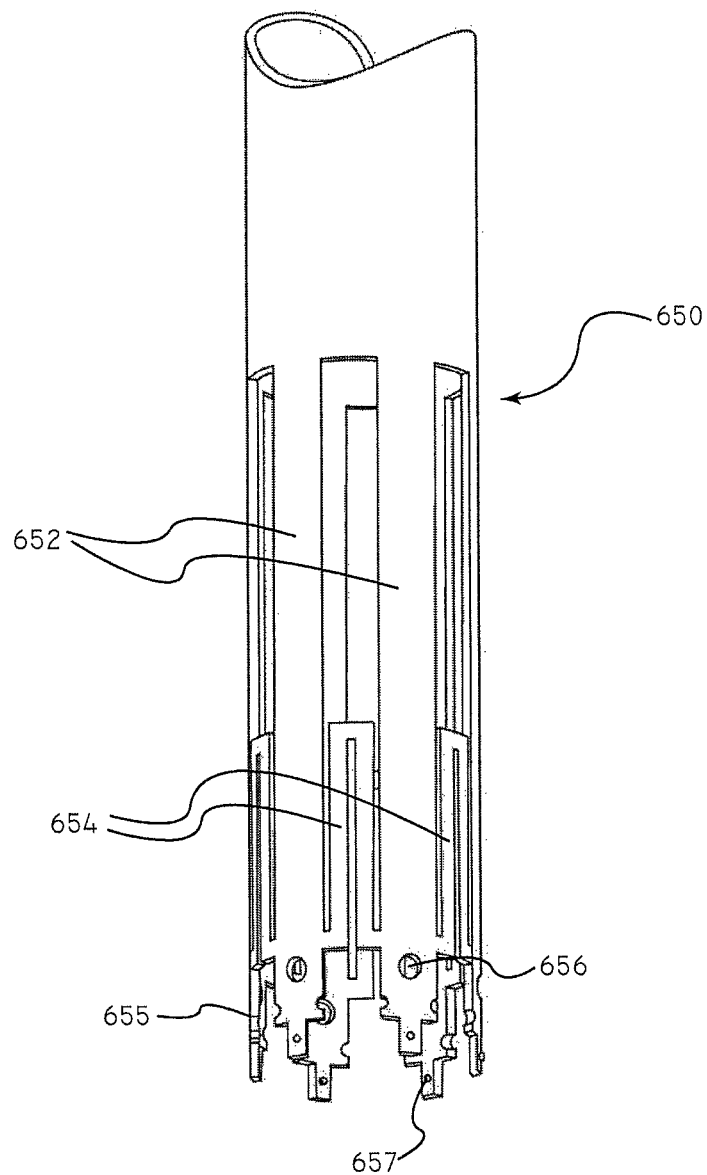


FIG 52A

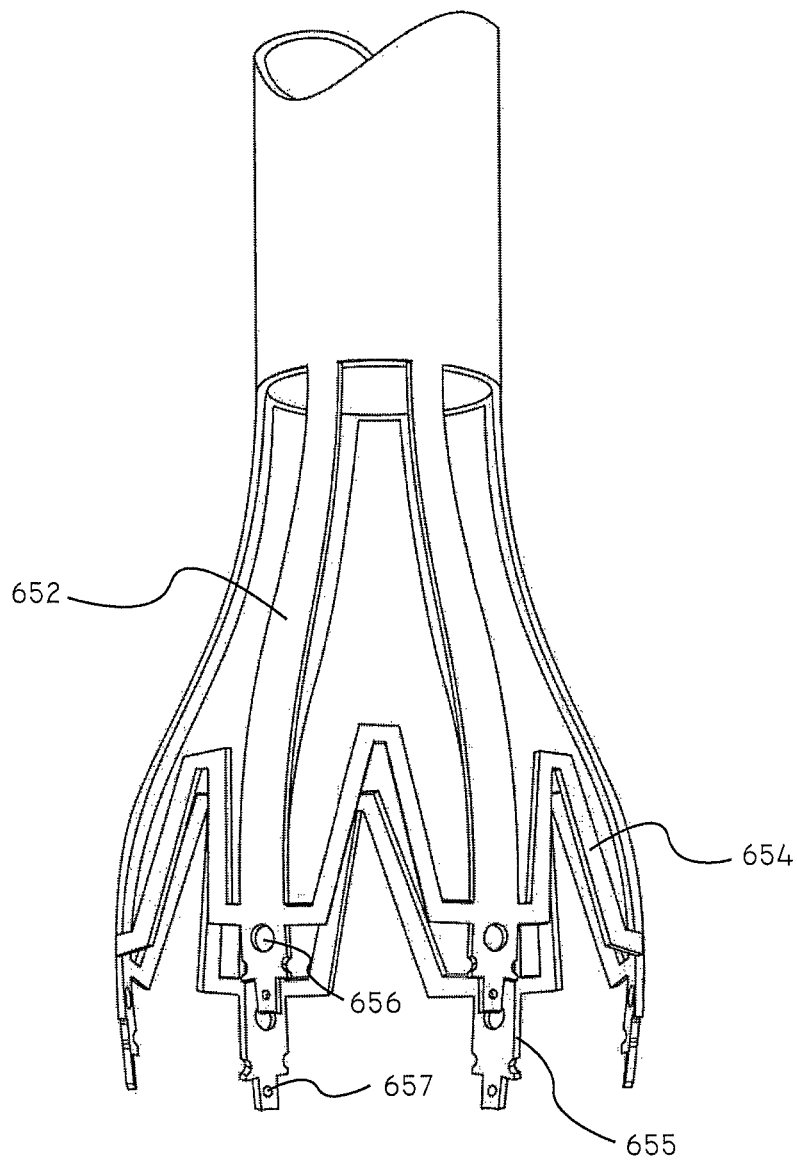


FIG 52B

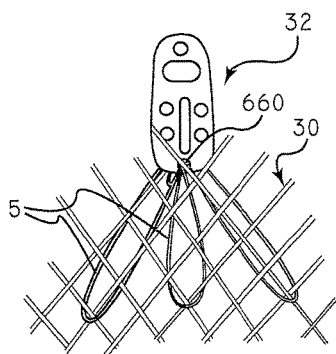


FIG 53A

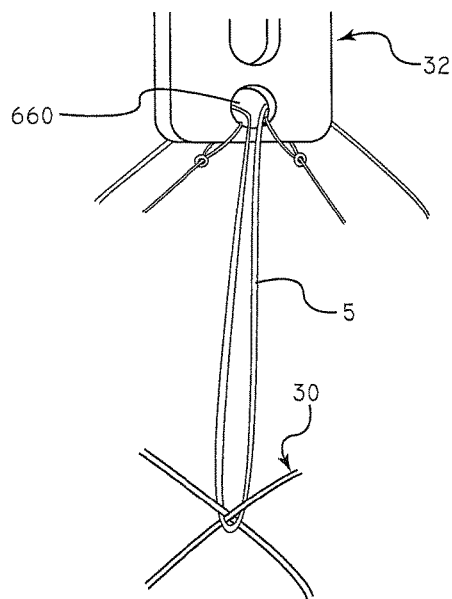


FIG 53B

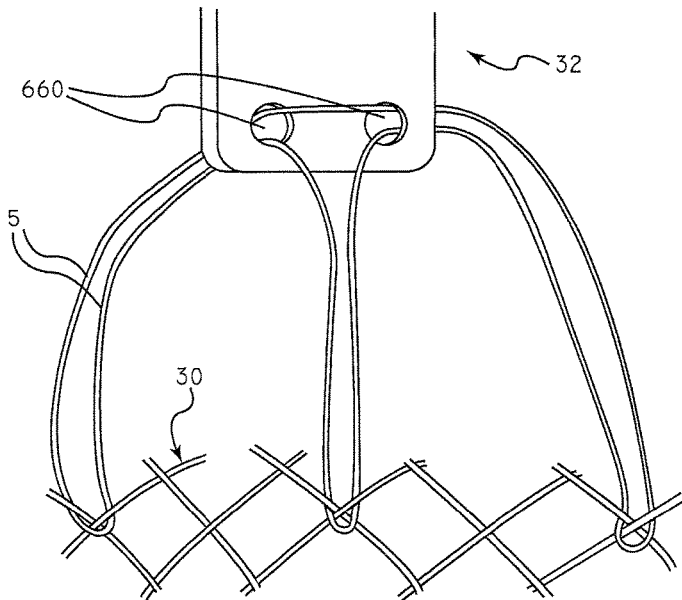


FIG 53C

METHODS AND APPARATUS FOR ENDOVASCULARLY REPLACING A HEART VALVE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 14/494,922, filed Sep. 24, 2014, now U.S. Pat. No. 9,320,599, which is a continuation of application Ser. No. 13/157,733, filed Jun. 10, 2011, now U.S. Pat. No. 8,858,620 which is a continuation of application Ser. No. 11/532,019, filed Sep. 14, 2006, now abandoned, which is a continuation of application Ser. No. 10/982,388, filed Nov. 5, 2004, now U.S. Pat. No. 7,959,666 which is a continuation-in-part of application Ser. No. 10/746,120, filed Dec. 23, 2003, now abandoned, the entire disclosure of each application being incorporated herein by reference.

BACKGROUND OF THE INVENTION

Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. Two to five percent of patients die during surgery.

Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. See, e.g., U.S. Pat. No. 6,168,614. In many of these procedures, the replacement valve is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve and to position the replacement valve in place of the native valve.

In the endovascular aortic valve replacement procedure, accurate placement of aortic valves relative to coronary ostia and the mitral valve is critical. Valve anchors comprising standard self-expanding stent systems are expected to have very poor accuracy in deployment, however. In a typical deployment procedure, the proximal end of the stent is not

released from the delivery system until accurate placement is verified by fluoroscopy. The stent may jump to another position once released, making it impossible to know where the ends of the stent will be after release with respect to the native valve, the coronary ostia and the mitral valve.

Also, visualization of the way the new valve is functioning prior to final deployment is very desirable. Due to the expected jumping action of some self-expanding anchors, and because the replacement valve may not be fully functional before final deployment, visualization of valve function and position prior to final and irreversible deployment may not be possible with these systems.

Another expected drawback of prior art self-expanding replacement heart valve systems is their relative lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. Expandable stent designs suitable for endovascular delivery for other purposes may not have sufficient radial strength to serve as replacement heart valve anchors. For example, there are many commercial arterial stent systems that apply adequate radial force against the artery wall to treat atherosclerosis and that can collapse to a small enough of a diameter to fit inside a delivery catheter without plastically deforming. However, when the stent has a valve fastened inside it, and that valve must reside within the heart, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls takes significantly more radial force, especially during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole will be directly transferred to the stent/vessel wall interface. Therefore, the amount of radial force required to keep the self-expanding stent/valve in contact with the vessel wall and not sliding will be much higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly causing it to migrate and dislodge completely. Simply increasing strut thickness of the self-expanding stent is not a good solution as it increases profile and/or a risk of plastic deformation of the self-expanding stent.

In view of drawbacks associated with previously known techniques for endovascularly replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

SUMMARY OF THE INVENTION

The invention includes methods of and apparatus for endovascularly replacing a heart valve of a patient. One aspect of the invention provides a method including the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve in an unexpanded configuration; and applying an external non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor through a plurality of anchor actuation elements to change the shape of the anchor, such as by applying a proximally and/or distally directed force on the anchor through anchor actuation elements to change the shape of the anchor. The anchor may be locked in its expanded configuration.

Another aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve, including: a replacement valve; an anchor; and a deployment tool comprising a plurality of anchor actuation elements adapted

to apply a non-hydraulically expanding or non-pneumatically expanding actuation force on the anchor to reshape the anchor. An anchor lock may be provided to lock the anchor in a deployed configuration, and there may also be a lock prevention element actuatable from outside the patient. Optionally, the anchor lock may be reversible.

Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering and deploying expandable devices in a patient and optionally detaching a deployment tool from the device.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIGS. 1A and 1B show replacement valve apparatus in accordance with the present invention. FIG. 1 illustrates the apparatus in a collapsed delivery configuration within a delivery system. FIG. 1B illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

FIGS. 2A-2F show an anchor of the apparatus of FIG. 1 in the collapsed delivery configuration and the expanded deployed configuration, as well as the full apparatus in the deployed configuration, and optional locking mechanisms for use with the apparatus.

FIGS. 3A-3E show the use of a replacement heart valve and anchor to replace an aortic valve.

FIGS. 4A and 4B show an alternative anchor lock embodiment in an unlocked configuration.

FIGS. 5A and 5B show the anchor lock of FIG. 4 in a locked configuration.

FIG. 6 shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

FIG. 7 shows the attachment and release mechanism of FIG. 6 in the process of being released.

FIG. 8 shows the attachment and release mechanism of FIGS. 6 and 7 in a released condition.

FIG. 9 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an un-deployed configuration.

FIG. 10 shows the replacement heart valve and anchor of FIG. 9 in a partially deployed configuration.

FIG. 11 shows the replacement heart valve and anchor of FIGS. 9 and 10 in a more fully deployed configuration but with the deployment tool still attached.

FIG. 12 shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

FIG. 13 shows the delivery and deployment apparatus of FIG. 12 in the process of deploying a replacement heart valve and anchor.

FIG. 14 shows a detail view of a variation of an anchor post.

FIGS. 15A and 15B show an alternative variation of the post having a lock alignment feature.

FIGS. 16A and 16B show a variation of the post having an alternative lock alignment feature.

FIG. 17 shows a variation of the post having an expansile element.

FIG. 18 shows a variation of the post with an alternative expansile element.

FIGS. 19A-19C show a variation of the post having an alternative lock alignment feature.

FIG. 20 shows the post variation of FIG. 14 in combination with an illustrative actuator and release actuator.

FIGS. 21A-21C show a variation of the post, actuator and release actuator that form an alternative releasable attachment mechanism.

FIGS. 22A-22C show another variation of the releasable attachment mechanism.

FIGS. 23A-23C show yet another variation of the releasable attachment mechanism.

FIGS. 24A and 24B show still another variation of the releasable attachment element.

FIG. 25 shows a variation of the post, actuator and anchor lock element having a reversible lock.

FIGS. 26A-26C show a variation of the actuator, lock actuator and release actuator.

FIG. 27 shows a variation of the anchor lock element having a lock alignment feature.

FIGS. 28A and 28B show expansion, locking and actuation of the releasable attachment mechanism of the apparatus of FIG. 27.

FIG. 29 shows another variation of the apparatus having an actuable lock prevention mechanism.

FIGS. 30A and 30B show a variation of the post that is configured to lock against the braid of the anchor.

FIGS. 31A-31C show actuation and release of a variation of the anchor lock element.

FIGS. 32A and 32B show another variation of a releasable actuation mechanism having a lock alignment mechanism which can be cut from a tube.

FIGS. 33A-33D show actuation of a variation of the anchor lock element that may be formed from a cut tube.

FIGS. 34A-34F show a variation of the post having an unlock actuator.

FIGS. 35A and 35B show another buckle variation of the anchor lock element.

FIG. 36 shows attachment of a variation of the anchor lock element to the anchor.

FIG. 37 shows a variation of the post and anchor lock element having a ratcheting lock.

FIGS. 38A and 38B show variations of the ratcheting lock.

FIGS. 39A-39H show actuation of another variation of the ratcheting lock.

FIGS. 40A-40C show a tubular variation of the ratcheting lock element.

FIGS. 41A-41C show a variation of the anchor lock element of FIG. 40.

FIGS. 42A and 42B show a variation of the apparatus of FIG. 41 comprising a lock alignment feature.

FIGS. 43A-43F show a method of actuating and adjusting the ratcheting lock of the apparatus of FIG. 41.

FIGS. 44A and 44B show a variation of an anchor/actuator.

FIGS. 45A-45C show detail views of the releasable attachment mechanism of the actuator of FIG. 44.

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FIGS. 46A-46C show a variation of the releasable attachment mechanism of FIG. 45.

FIGS. 47A-47C show another variation of the releasable attachment mechanism.

FIGS. 48A-48C show yet another variation of the releasable attachment mechanism.

FIGS. 49A-49N show variations of a release actuator used in conjunction with the releasable attachment mechanism of FIG. 45.

FIGS. 50A and 50B show detail views of an embodiment of the delivery system/deployment tool.

FIGS. 51A and 51B show the delivery system/deployment tool of FIG. 50 releasably attached to apparatus 10, and detached from the apparatus.

FIGS. 52A and 52B show a variation of the delivery system/deployment tool of FIGS. 50 and 51 wherein the actuators extend from a unitary structure.

FIGS. 53A-53C show various ways to connect elements to the anchor of the replacement valve apparatus.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to apparatus and methods for endovascularly delivering and deploying a prosthesis, e.g., an aortic prosthesis, within and/or across a patient's native heart valve, referred to hereinafter as replacing the patient's heart valve. A delivery system and/or deployment tool is provided including a sheath assembly and a guidewire for placing the prosthetic apparatus endovascularly within the patient and a user control allowing manipulation of the prosthetic apparatus from external to the patient through the application of a non-hydraulically expanding or non-pneumatically expanding force on the anchor. A hydraulically or pneumatically expanding force would be, for example, a force applied to the anchor by a balloon expanded within the anchor. In certain embodiments, the application of a non-hydraulically expanding or non-pneumatically expanding force could include the use of a hydraulic component transmitting a proximally or distally directed force on an anchor.

The apparatus includes an anchor and a replacement valve. The anchor includes an expandable anchor such as a braid. In preferred embodiments, the expandable braid includes closed edges, but the edges may alternatively be open. The replacement valve is adapted to be secured within the anchor, and as such, be delivered endovascularly to the patient's heart to replace one of the patient's native heart valves. More preferably, the apparatus and methods of the present invention contemplate replacement of the patient's aortic valve.

FIGS. 1A and 1B illustrate one embodiment of a delivery system/deployment tool and apparatus in accordance with the present invention. As seen in FIG. 1A, apparatus 10 may be collapsed for delivery within delivery system/deployment tool 100. Delivery system 100 includes guidewire G, nosecone 102, anchor actuation elements 106, multi-lumen shaft or catheter 108 having optional central lumen 109 and a plurality of circumferentially disposed lumens Lu, external sheath 110 having optional proximal handle 111, and control handle 120. Nosecone 102 may, for example, be manipulated via a shaft extending through central lumen 109 of multi-lumen catheter 108.

Anchor actuation elements 106 preferably comprise both proximal anchor actuation elements and distal anchor actuation elements. The proximal anchor actuation elements may, for example, comprise actuators 106a that are releasably

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coupled to a proximal region of anchor 30 of apparatus 10 via releasable attachment mechanisms for manipulating a proximal region of apparatus 10. The distal anchor actuation elements may comprise actuators 106b that are releasably coupled to a distal region of anchor 30 via releasable attachment mechanisms for manipulating the distal region of apparatus 10. In some embodiments, the distal anchor actuation elements may comprise posts or anchor attachment mechanisms 32 of anchor 30 and the releasable attachment mechanisms connecting actuators 106b to posts 32. In an alternative configuration, the proximal anchor actuation elements may be releasably coupled to a proximal region of apparatus 10 through posts and releasable attachment mechanisms for manipulation of a proximal region of the apparatus, while the distal anchor actuation elements may connect to a distal region of anchor 30 via releasable attachment mechanisms to manipulate a distal region of the apparatus. As another alternative, both proximal and distal anchor actuation element may connect to anchor 30 via releasable attachment mechanisms.

In the embodiment shown in FIG. 1, actuators 106a may, for example, include stiff finger elements extending from a distal region of multi-lumen shaft 108, while actuators 106b may include control wires (e.g., stands of suture, or metal or polymer wires) which pass through one or more lumens Lu of shaft 108. Release actuators 112 for the releasable attachment mechanisms for both sets of actuators also may pass through one or more lumens Lu of shaft 108. The release actuators may comprise, for example, control wires (e.g., strands of suture, or metal or polymer wires), covers, mandrels, elongated elements, friction surfaces, wrap portions, interference shapes, etc. The release actuators preferably are movable relative to anchor actuation elements 106, e.g., via control handle 120.

Control handle 120 is coupled to multi-lumen shaft 108. Knob 122 disposed in slot 123 may actuate release actuators 112 that couple actuators 106a of anchor actuation elements 106 to apparatus 10. Likewise, knob 124 disposed in slot 125 may actuate release actuators 112 that couple actuators 106b of anchor actuation elements 106 to posts 32 of anchor 30 of apparatus 10. Handle 120 also comprises knob 126 for, e.g., manipulating the actuators 106b to control movement of the distal region of apparatus 10 relative to its proximal region. Conversely, controlled movement of the proximal region of apparatus 10 relative to its distal region may be achieved by holding knob 126 stationary while advancing or retracting handle 120. Knob 126 optionally may move actuators 106b in unison with their concomitant release actuators 112.

Apparatus 10 comprises anchor 30 and replacement valve 20. Anchor 30 preferably comprises a braid. Such braid can have closed ends at either or both its ends. Replacement valve 20 is preferably coupled to the anchor along posts 32, e.g., along a valve attachment structure, such as a tab and/or a plurality of holes. Posts 32, therefore, may function as valve supports and may be adapted to support the replacement valve within the anchor. In the embodiment shown, there are three posts, corresponding to the valve's three commissural attachment points. The posts can be attached to the braid portion of anchor 30. The posts can be attached to the braid's distal end, as shown in FIG. 2A, central region, or proximal end. Replacement valve 20 can be composed of a synthetic material and/or may be derived from animal tissue. Replacement valve 20 is preferably configured to be secured within anchor 30.

Anchor 30 comprises a plurality of anchor lock elements 34, e.g., buckles 34, attached to its proximal region, one for each post 32. Posts 32 may comprise a lock element that

forms a two-part locking mechanism with anchor lock elements **34** for maintaining anchor **30** in a deployed or expanded configuration (e.g., as illustrated in FIGS. 1B, 2B and 2C).

In this embodiment, anchor **30** is formed from a collapsible and expandable wire braid. Anchor braid **30** is preferably self-expanding and is preferably formed from a material such as Nitinol, cobalt-chromium steel or stainless steel wire using one or more strands of wire. Delivery and deployment of braided anchor **30** is similar to the delivery and deployment of the anchors described in U.S. patent application Ser. No. 10/746,120. Specifically, in one embodiment described below, during deployment braided anchor **30** is actively foreshortened by proximally retracting the actuators **106b** relative to the actuators **106a** to expand and lock the anchor in place. In some embodiments, foreshortening may expand anchor **30** to a radially symmetrical, bilaterally symmetrical, or asymmetrical expanded shape. The foreshortening step can include expanding a first region of the anchor to a first diameter and a second region of the anchor to a second diameter larger than the first diameter. A third region may also be expanded to a diameter larger than the first diameter. The expansion of various regions of the anchor (e.g., the distal region) can be especially useful in locating the aortic valve and centering the anchor within it. Preferably, the secured anchor does not interfere with the mitral valve or the ostia. In some embodiments, the anchor is allowed to self-expand prior to the foreshortening step.

As seen in FIG. 1, after endovascular delivery through sheath **110** to the vicinity of the patient's native valve (such as the aortic valve), apparatus **10** may be expanded from the collapsed delivery configuration of FIG. 1A to the expanded deployed configuration of FIG. 1B using delivery system/deployment tool **100**. To deploy apparatus **10**, external sheath **110** may be retracted relative to apparatus **10** by proximally retracting sheath handle **111** relative to control handle **120**. Sheath **110** is thereby removed from the exterior of apparatus **10**, permitting the anchor **30** to self-expand. For example, if anchor braid **30** is composed of a shape memory material, it may self-expand to or toward its "at-rest" configuration. This at-rest configuration of the braid can be, for example its expanded configuration, a collapsed configuration, or a partially expanded configuration between the collapsed configuration and the expanded configuration, or some combination. In preferred embodiments, the anchor's at-rest configuration is between the collapsed configuration and the expanded configuration. Depending on the at-rest diameter of the braid and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

In its collapsed configuration, anchor **30** preferably has a collapsed delivery diameter between about 3 to 30 Fr, or more preferably 6 to 28 Fr, or more preferably 12 to 24 Fr. In some embodiments, anchor **30** in its collapsed configuration will have a length ranging from about 5 to about 170 mm, more preferably from about 10 to about 160 mm, more preferably from about 15 to about 150 mm, more preferably from about 20 to about 140 mm, or more preferably from about 25 mm to about 130 mm.

Similarly, in its expanded configuration, anchor **30** preferable has a diameter ranging between about 10 to about 36 mm, or more preferably from about 24 to about 33 mm, or more preferably from about 24 to about 30 mm. In some embodiments, anchor **30** in its expanded configuration will have a length ranging from about 1 to about 50 mm, more

preferably from about 2 to about 40 mm, more preferably from about 5 to about 30 mm, or more preferably from about 7 to about 20 mm.

Overall, the ratio of deployed to collapsed/sheathed lengths is preferably between about 0.05 and 0.5, more preferably about 0.1 to 0.35, or more preferably about 0.15 to 0.25. In any of the embodiments herein, anchor **30** in its expanded configuration preferably has a radial crush strength that maintains the anchor substantially undeformed in response to a pressure of up to about 0.5 atm directed substantially radially inward toward the central axis, or more preferably up to about 2 atm directed substantially radially inward toward the central axis. In addition, in any of the embodiments herein, the anchor preferably has an axial spring constant of between about 10 to 250 g/cm, more preferably between about 20 to 200 g/cm, or more preferably between about 40 to 160 g/cm. In addition, in any of the embodiments herein, the anchor is preferably adapted to support the replacement valve at the anchor site in response to a differential pressure of up to about 120 mm Hg, more preferably up to about 240 mm Hg, or more preferably up to about 320 mm Hg.

These parameters are not intended to be limiting. Additional parameters within the scope of the present invention will be apparent to those of skill in the art.

As seen in FIG. 1B, anchor **30** may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor **30** during endovascular deployment. In some embodiments, foreshortening of the apparatus involves applying a distally directed force on the proximal end of the anchor by one or more anchor actuation elements to move the proximal end of the anchor distally while maintaining the position of the distal end of the anchor. For example, the proximal region of anchor **30** may be pushed distally by certain anchor actuation elements **106**, e.g., actuators **106a**. Alternatively, foreshortening of the apparatus involves applying a proximally directed force on the distal end of the anchor by one or more anchor actuation elements to move the distal end of the anchor proximally while maintaining the position of the proximal end of the anchor. For example, the distal region of anchor **30** may be pulled proximally via a proximally directed force applied by post actuation elements **106b**, this force opposed by anchor actuators **106a**.

Anchor actuation elements **106** preferably are adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

The distal anchor actuation elements may include, for example, actuators **106b** and/or release actuators **112** that are controlled, e.g., by control knobs **124** and **126** of control handle **120**. Similarly, the proximal regions of anchor **30** may be pushed distally via proximal anchor actuation elements, e.g., actuators **106a**, at the proximal region of the anchor. The proximal anchor actuation elements facilitate application of a distally directed force to the proximal end of anchor **30** to move or constrain the proximal end of the

anchor distally and are controlled through motion of shaft **108** relative to the distal anchor actuation elements. Control knob **122** of control handle **120** may control release actuators **112** for releasing the proximal anchor actuation elements from the braid. The proximal anchor actuation elements may be further adapted to expand as the proximal end of the anchor expands radially during application of a distally directed force on the proximal end of the anchor. Preferably, the proximal anchor actuation elements apply a distally directed force on the proximal end of the anchor system through a plurality of actuators **106a** in order to expand the braid of anchor **30**. Such braid expansion optionally may be assisted via inflation of a balloon catheter (see FIGS. **12** and **13**) reversibly disposed within apparatus **10**, as described in U.S. patent application Ser. No. 10/746,120.

In the fully deployed configuration, lock elements of posts **32** and anchor lock elements or buckles **34** of anchor **30** may be used to lock and maintain the anchor in the deployed configuration. Apparatus **10** may be repositioned or retrieved from the patient until the lock elements of posts **32** have been interlocked with anchor lock elements **34** of anchor **30** to form lock **40**. In one embodiment, actuators **106b** and attendant release actuators **112** comprise control wires attached to posts **32** that are threaded through buckles **34** so that the proximally directed force exerted on posts **32** by the control wires during deployment pulls a lock element of posts **32** toward and through buckles **34** to form lock **40**. In this manner, the control wires may act as both anchor actuators and lock actuators.

Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus **10** during or post-deployment. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, i.e., even after actuation of lock **40**.

Locks used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the anchor lock elements at the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion (see, e.g., FIG. **2F**). Such locking mechanisms may, for example, comprise ratchets having multiple lock locations. Furthermore, lock alignment features may be provided to facilitate alignment of the post and anchor lock elements, such as a hinge or an oversized width of the post or anchor lock elements. Further still, lock prevention mechanisms may be provided to preclude locking until desired by a medical practitioner.

When apparatus **10** is placed across a patient's diseased heart valve, anchor **30** may be used to displace the patient's native valve leaflets, and replacement valve **20** will thereafter serve in place of the native valve. After final positioning and expansion, apparatus **10** may be decoupled from delivery system **100** by decoupling the proximal and distal anchor actuation elements **106** from the apparatus via releasable attachment mechanisms, e.g., by decoupling proximal actuators **106a** from braided anchor **30** and distal actuators **106b** from posts **32** of the anchor via the releasable attachment mechanisms. Moving release actuators **112**, e.g., using knobs **122** and **124** of handle **120**, may, for example, actuate the releasable attachment mechanisms. Preferably, the releasable attachment mechanisms may be actuated by moving the release actuator(s) less than about 1 inch. After decoupling, delivery system/deployment tool **100** may be removed from the patient, thereby completing endovascular replacement of a patient's heart valve.

Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

FIGS. **2A-2C** show further details of anchor **30** of apparatus **10**. FIG. **2A** shows the apparatus in a collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. FIGS. **2B** and **2C** show the anchor and valve in an expanded and locked configuration.

As shown in FIG. **2B**, anchor **30** illustratively has three posts and three buckles. As seen in FIG. **2C**, the three leaflets of replacement valve **20** may be coupled to the three posts **32** along valve support structures. Thus, posts **32** act as valve supports. The posts, unlike the braid, do not collapse or expand. In some embodiments, a post **32** has one or more proximal slots **33**, at least one proximal hole **36a** and at least one distal hole **36b**. Leaflet tissue may, for example, be passed through slot **33** and sutured in place via suture routed through one or more proximal holes **36a**. In this manner, slot(s) **33** and hole(s) **36a** may form a valve support structure. Alternative valve support structures known in the art for fixing valve leaflets to posts may also be employed.

Posts **32** may be coupled to anchor braid **30** via one or more distal holes **36b**. For example, anchor braid **30** may be woven through holes **36b**, or a suture or wire may be routed through holes **36b** and tied to the braid. Yet another proximal hole (not shown) in post **32** serves as an anchor lock element that interfaces with the anchor lock element provided by buckle **34** to form lock **40**. Buckles **34** may likewise be attached to anchor braid **30** via weaving or suturing.

Alternative locks may be used to lock the anchor of the present invention in the foreshortened configuration, as shown, e.g., in FIGS. **2D-2F**. Preferably, a lock of the present invention can have multiple locking options such that locking can confer a plurality of amounts of expansion. Furthermore, the locking option can be employed asymmetrically to confer non-cylindrical shapes to the anchor. In FIG. **2D**, lock **40'** comprises male lock element **44** disposed on post **32** and anchor lock element **34** disposed on braided anchor **30**. Anchor lock element **34** illustratively comprises triangular protrusion or eyelet **42** of anchor **30**. The triangular shape of female lock element **42** may facilitate mating of male lock element **44** with the female lock element without necessitating deformation of the male lock element. One or more holes **45** may be provided through post **32**, e.g., for releasably attaching an actuator **106b** to the post.

In FIG. **2E**, lock **40''** comprises alternative male lock element **44'** having multiple in-line arrowheads **46** along posts **32**. Each arrowhead comprises resiliently deformable appendages **48** to facilitate passage through female lock element **42'**, which illustratively comprises a rounded eyelet. Appendages **48** optionally comprise holes **49**, such that releasable lock prevention mechanism **47**, illustratively a control wire, may pass through the holes to constrain the appendages in the deformed configuration. To actuate lock **40''**, one or more arrowheads **46** of male lock element **44'** are drawn through female lock element **42'**, e.g., via a post/lock actuator, and the lock prevention mechanism is removed from holes **49**, thereby causing appendages **48** to resiliently expand and actuate lock **40''**.

Advantageously, providing multiple arrowheads **46** along posts **32** yields a ratchet that facilitates in-vivo determina-

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tion of a degree of foreshortening and expansion imposed upon anchor 30. Furthermore, optionally constraining appendages 48 of arrowheads 46 via mechanism 47 prevents actuation of lock 40" (and thereby deployment of apparatus 10) even after male element 44' has been advanced through female element 42'. Only after a medical practitioner has removed lock prevention mechanism 47, which constrains appendages 48, is lock 40" fully engaged and is deployment no longer reversible.

Lock 40'" of FIG. 2F is similar to lock 40" of FIG. 2E, except that holes 49 on appendages 48 have been eliminated, and the lock prevention mechanism comprises overtube or cover 47. Overtube 47 constrains appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Lock 40'" may, for example, be actuated by applying a proximally-directed force to actuator 106b. Actuator 106b illustratively comprises a control wire releasably disposed through hole 45 in post 32. Lock prevention mechanism 47 then is withdrawn proximally relative to anchor 30, which causes the appendages to resiliently expand, thereby fully actuating lock 40'".

Referring now to FIG. 3 in conjunction with FIGS. 1 and 2, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 and delivery system/deployment tool 100 is described. As seen in FIG. 3A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is endovascularly advanced over guidewire G, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta A to the patient's diseased aortic valve AV. Nosecone 102 precedes sheath 110 in a known manner. In FIG. 3B, sheath 110 is positioned such that its distal region is disposed within left ventricle LV of the patient's heart H.

Apparatus 10 is deployed from lumen Lu of sheath 110, for example, under fluoroscopic guidance by proximally retracting proximal handle 111 of sheath 110 relative to shaft 108, such that anchor 30 of apparatus 10 dynamically self-expands to the partially deployed configuration of FIG. 3C. Advantageously, apparatus 10 may be retracted within lumen Lu of sheath 110 by retracting shaft 108 relative to the sheath, and thereby retracting actuators 106a coupled to anchor 30 relative to sheath 110. In this manner, anchor 30 may be retrieved even after the anchor has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets L. When properly aligned, a distal region of anchor 30 preferably is disposed distal of the leaflets, while a central region of the anchor is disposed across the leaflets and a proximal region is disposed proximal of the leaflets.

Once properly aligned, actuators 106b are proximally retracted relative to actuators 106a, e.g., via knob 126 of handle 120, to impose foreshortening upon anchor 30 and further expand apparatus 10 to the fully deployed configuration, as in FIG. 3D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus An, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. Lock 40 formed by engaging post lock elements 44 of posts 32 with anchor lock elements 34 of anchor 30 maintains imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter completely regulated by apparatus

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10, although valve 20 is functional during deployment as well. Deployment of apparatus 10 advantageously is fully reversible until the locks have been actuated. Releasable lock prevention mechanisms may be provided to ensure that the locks are not actuated prematurely. Furthermore, the locks may be reversible, such that apparatus 10 may be retrieved or repositioned even after actuation of the locks.

Once apparatus 10 is fully expanded and locked in the expanded configuration, actuators 106a are decoupled from anchor 30 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106a via knob 122 of handle 120. Likewise, actuators 106b are decoupled from posts 32 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106b via knob 124 of handle 120. As seen in FIG. 3E, delivery system 100 then may be removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or to reduce paravalvular regurgitation.

FIGS. 4 and 5 illustrate anchor lock mechanisms depicted in FIG. 4 in the locked configuration. FIGS. 4 and 5 should be viewed as if cylindrical anchor 30 has been cut open and laid flat. Posts 32 coupled to anchor 30 illustratively comprise actuator attachment elements 200 and lock elements 202, e.g., eyelets or holes formed through the posts. Anchor 30 comprises anchor lock elements 34, illustratively buckles, which are configured to mate with lock elements 202 of the posts. Posts 32 and buckles 34 may, for example, be connected to braided anchor 30 by inter-weaving the posts and the buckles into the braid of the anchor. Alternatively, the posts and/or buckles may be sutured, soldered, welded, connected with adhesive, etc., to the anchor. The commissures of previously described replacement valve 20 may be connected to posts 32 along all or a portion of their lengths.

Lock elements 202 of posts 32 mate with tabs 210 extending into holes 212 in anchor lock elements 34. To lock, actuators 106b, which releasably pass through actuator attachment elements 200 of posts 32 and holes 212 of anchor lock elements 34, are pulled proximally by anchor actuators 106b (illustratively control wires) with respect to the proximal end of braided anchor 30 to draw posts 32 through holes 212 so that tabs 210 engage lock elements 202 of posts 32. Also shown are unlocking actuators 220, illustratively control wires, which pass through anchor lock eyelets 214 in anchor lock elements 34. If needed, during the procedure, the user may pull on unlocking actuators 220, thereby reversing orientation of tabs 210, releasing the anchor and allowing for repositioning of the device or its removal from the patient. Only when final positioning as desired by the operating physician is achieved, would unlocking actuators 220, as well as actuators 106b, be removed from apparatus 10 and the patient.

Referring now to FIGS. 6-8, an alternative way of releasing the connection between the anchor (or post, etc.) and the anchor actuation elements is described. In FIG. 6, release actuator 112, illustratively a control wire, extends through actuator 106a from outside the patient, loops through the proximal region of braided anchor 30 and extends partially back into actuator 106a. The doubled up portion of release actuator 112 creates a force fit within actuator 106a that maintains the release actuator's position with respect to the actuator 106a when all release actuators 112 within actuators 106a are pulled proximally, e.g., when applying a proximally directed force on anchor 30. When a single release actuator 112 is pulled proximally, however, the frictional fit

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between that release actuator and the actuator 106a in which it is disposed is overcome, enabling the end 113 of release actuator 112 to pull free of actuator 106a, as shown in FIGS. 7 and 8, thereby releasing anchor 30. In an alternative embodiment, the doubled up portion of release actuator 112 may extend proximally to, e.g., control handle 120. In such an embodiment, expansion of anchor 30 may be achieved by proximally retracting both ends of the doubled up release actuator 112 via the control handle, while release of actuator 106a may be achieved by pulling on one end of release actuator 112.

FIGS. 9-11 show additional views of apparatus 10. Anchor 30 is made of a metal braid, such as Nitinol or stainless steel. Replacement valve 20 is disposed within anchor 30. Anchor 30 is actuated in substantially the same way as described previously through the application of proximally and distally directed forces from distal anchor actuators (not shown) and actuators 106a.

FIGS. 12 and 13 show another embodiment of the delivery and deployment apparatus of the invention. In this embodiment, the nosecone (e.g., element 102 of FIGS. 1A and 3) is replaced by angioplasty balloon catheter 230. Thus, angioplasty balloon catheter 230 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of anchor actuation elements 106 as described above, balloon catheter 230 is retracted proximally within the expanded anchor and valve and may be inflated to further expand the apparatus 10, as desired. Optionally, a separate balloon catheter or valvuloplasty catheter may be advanced within apparatus 10 after expansion thereof to achieve additional expansion of the apparatus.

Referring now to FIG. 14, a detail view of a variation of post 32 is described. In FIG. 14, post 32 illustratively comprises actuator attachment element 250 for attaching the post to an actuator 106b; post lock element 252, illustratively a slot, for interlocking post 32 with an anchor lock element 34; valve attachment structure 254, comprising slot 255 and a plurality of holes 256, for attaching replacement valve 20 to the post (a tab of the valve may be passed through slot 255, then sewn to the back of the post through holes 256); and braid attachment element 258 for attaching the post to a distal region of anchor 30. The braid of anchor 30 may, for example, be interwoven through braid attachment element 258. Post 32 may be fabricated from a variety of materials, e.g., metallic materials such as stainless steel, and may be laser cut, die cast, etc. In this variation of post 32, valve 20 is disposed distal of lock element 252. In alternative variations, the valve may be attached to the post proximal of the lock element or in-line with the lock element (i.e., neither proximal nor distal to the lock).

FIG. 15 provide an alternative variation of post 32. In FIG. 15, post 32 comprises lock element 260 having lock alignment feature 262, illustratively hinge 263. Hinge 263 allows lock element 260 to rotate from a position in line with post 32, as in FIG. 15A, to a position out of alignment with the post, as in FIG. 15B, thereby facilitating alignment with an anchor lock element 34. As shown, post 32 further comprises actuator attachment element 264, illustratively an eyelet, valve support structure 266 having slot 267 and a plurality of holes 268, and braid attachment element 269.

FIG. 16 illustrate an alternative variation of lock alignment feature 262 comprising spring 270. As with hinge 263, spring 270 facilitates alignment of post lock element 260 with an anchor lock element 34 by allowing the post lock element to rotate from a position in line with post 32, as in FIG. 16A, to a position out of alignment with the post, as in

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FIG. 16B. Spring 270 also applies a restoring force that urges post lock element 260 back into alignment with post 32. Furthermore, spring 270 may facilitate dynamic elongation of post 32 in response to axial tension. This elongation may facilitate axial lengthening of anchor 30 in response to radially inward compression applied to the anchor.

With reference to FIG. 17, another variation of post 32 is provided comprising expansion zone 280, which may, for example, comprise a laser cut feature along post 32. Expansion zone 280 facilitates dynamic elongation of post 32 in response to axial tension applied to the post, which facilitates axial lengthening of anchor 30 in response to radially inward compression applied to the anchor. FIG. 18 illustrates an alternative expansile element 290 comprising a curved wire or rod that may be elongated and straightened through application of axial tension to facilitate axial lengthening of the anchor in response to radially inward compression applied to the anchor (and thereby axial tension applied to post 32 via interaction between post lock element 260 and an anchor lock element 34).

Element 290 additionally or alternatively may serve as a lock alignment feature. In such a configuration, element 290 optionally may not be expansile. More generally, post 32 may comprise proximal and distal ends connected by a tensile member.

FIG. 19 illustrate another variation of post 32 having another alternative lock alignment feature 262. In FIG. 19, actuator 106b applies a proximally-directed force which brings post lock element 260 and anchor lock element 34 proximate to one another allowing the system to lock. Anchor lock element 34 defines a lock width W_1 .

In this embodiment, lock alignment feature 262 comprises post lock element lock area or width W_2 that is substantially wider than the lock width W_1 , for example, at least about twice as wide. This increased width enhances the probability of interlocking the post and anchor lock elements, even at sharply misaligned angles. In FIG. 19, post 32 and anchor lock element 34 are disposed at an illustrative misalignment angle of about 10° .

Referring now to FIG. 20, the variation of post 32 of FIG. 14 is shown in combination with an illustrative actuator 106b and release actuator 112. In FIG. 20, actuator 106b illustratively comprises rod 300 having post attachment element 302 that mates with actuator attachment element 250 of post 32. Angled camming surfaces 304 and 305 of post attachment element 302 and actuator attachment element 250, respectively, form an interface between post attachment element 302 and actuator attachment element 250. Proximal movement of actuator 106b with respect to post 32 is translated by the camming surfaces into a lateral force between the two elements that acts to separate and release post 32 from actuator 106b. Release actuator 112, illustratively tube 310, may be advanced over actuator 300 to cover the camming surface interface of the post and the actuator 106b, thereby forming a releasable attachment mechanism for securing the post to the actuator even during application of axial tension to the actuator. To separate post 32 from actuator 106b, e.g., after expansion and locking of anchor 30, release actuator 112 may be retracted relative to actuator 106b to the position shown in FIG. 20, thereby removing a constraint from camming surfaces 304 and 305 and allowing the post and actuator to be pulled apart. Release actuator 112 preferably is retracted less than about 1 inch relative to the actuator 106b in order to actuate the releasable attachment mechanism, e.g., to remove constraint from camming surfaces 304 and 305.

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Referring now to FIG. 21, an alternative releasable attachment mechanism for attaching a variation of post 32 to a variation of actuator 106b is described. In FIGS. 21A and 21B, post 32 having actuator attachment element 320, illustratively an enlarged proximal opening within the post, is interference fit with post attachment element 330 of actuator 106b, illustratively an enlarged bulb, knob or other distal protrusion of the actuator. The slope of element 330 provides a camming surface that interfaces with an inside surface of opening 320. The angle of the camming interface between element 330 and opening 320 translates proximal movement of actuator 106b with respect to post 32 into a lateral movement between actuator 106b and post 32, thereby separating these elements. Release actuator 112, illustratively tube 310, covers the interference fit releasable attachment mechanism to preclude lateral movement of the post attachment element relative to the actuator attachment element, thereby releasably attaching the post to the actuator 106b. In FIG. 21C, tube 310 is retracted relative to the post and actuator, which permits lateral movement between the post and actuator attachment elements, thereby separating actuator 106b from post 32. If tube 310 has not been retracted, of course, proximal movement of actuator 106b moves post 32 and the distal portion of the anchor proximally.

FIG. 22 illustrate a variation of the releasable attachment mechanism of FIG. 21. In the variation of FIG. 22, actuator attachment element 320 of post 32 is deformable from a substantially round profile to an oval or "figure eight" profile by advancement of release actuator 112 over the attachment element. This forms a releasable attachment mechanism. In the deformed profile of FIGS. 22A and 22B, post attachment element 330 of actuator 106b is interference fit with the deformed actuator attachment element of post 32. In FIG. 22C, retraction of release actuator 112 relative to the post and actuator allows actuator attachment element 320 to resiliently resume its un-deformed or at-rest configuration, thereby permitting separation of post 32 from actuator 106b. Actuator attachment element 320 may, for example, be fabricated from a shape memory material, such as Nitinol. A camming surface 331 on post attachment element 330 and a corresponding surface on the inner portion of element 320 translate proximal movement of actuator 106b with respect to post 32 into lateral movement of element 330 with respect to element 320 when release actuator 112 has been retracted.

In the variation of FIG. 23, post attachment element 330 is deformable (as in FIGS. 23A and 23B), and anchor attachment element 320 may be interference fit with the post attachment element. FIG. 23C shows the post attachment element 330 in its at-rest configuration after tube 310 has been retracted, thereby releasing anchor attachment element 320. As will be apparent, for many or all of the two-part locking or attachment element elements described herein, the position of the elements may be reversed.

In FIG. 24, post attachment element 330 comprises wrap portion 332 that may be inserted through anchor attachment element 320, illustratively an eyelet, wrapped backwards, then covered with release actuator tube 310 to constrain the wrap portion 332 in the wrapped configuration, as in FIG. 24A. Release actuator tube 310 may be retracted relative to the wrap portion to resiliently or dynamically (e.g., by retracting actuator 106b relative to post 32) reshape the wrap portion to a substantially straight configuration for releasing the attachment between the post and the actuator, as in FIG. 24B. Wrap portion 332 preferably is fabricated from a shape memory material, such as Nitinol, or a resilient material, such as spring steel.

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FIG. 25 shows another variation of the post, actuator and anchor lock element. In FIG. 25, post 32 comprises post lock element 260 and actuator attachment element 264, illustratively an eyelet, through which actuator 106b is reversibly disposed. Anchor lock element 34 illustratively comprises a buckle, which may, for example, be formed from a cut tube or a bent resilient material. Anchor lock element 34 comprises anchor or braid attachment element 340 for attaching the buckle to anchor 30, and tab 342 for interlocking the buckle with post lock element 260, which illustratively is a slot formed through post 32. Actuator 106b therefore actuates the post (and therefore the distal end of the anchor to which the post is attached) as well as the anchor lock. Actuator 106b may be released from the post (and therefore from the anchor) by pulling one end of the control wire proximally to draw the control wire through and out of opening 264.

Anchor lock element 34 also comprises optional unlock actuator attachment 344, illustratively a pair of eyelets, through which unlock actuator 350 is releasably coupled to anchor lock element 34. Unlock actuator 350 illustratively comprises a control wire. Upon locking of tab 342 of buckle 34 within slot 260 of post 32, a proximally-directed force applied to unlock actuator 350 may remove the tab from the slot, thereby unlocking buckle 34 and post 32 and permitting the anchor to contract and elongate. Unlocking may be utilized, for example, to reposition or retrieve the anchor and valve apparatus even after the apparatus has been locked in the fully deployed configuration, as described previously with respect to FIG. 3.

FIG. 26 show another variation of the actuator, the lock actuator and the release actuator. As with other anchor lock elements, anchor lock element 34 in this embodiment is attached to a proximal end of the anchor, and the distal end of post 32 is attached to a distal end of the anchor. The anchor is not shown in FIG. 26 for ease of illustration. For the purposes of illustration, the unlock actuator also is not shown in FIG. 26.

As shown, actuator 106b actuates both post 32 (and therefore the distal end of the anchor to which the post is attached) and the lock formed between post lock element 260 and anchor lock element 34. In FIG. 26A, release actuator 112 passes through actuator 106b to actuate the releasable attachment mechanism between post 32 and actuator 106b. FIG. 26B provides a detail view of the releasable attachment mechanism. Actuator 106b comprises wrap portion 360 that passes through actuator attachment element 264 and wraps around the end of post 32. Wrap portion 360 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material.

Wrap portion 360 further comprises first opening 362 for engaging release actuator 112, illustratively a wire or rod that passes through lumen Lu of actuator 106b. The walls of the lumen act a linear bearing and/or motion guide during advancement and retraction of the release actuator relative to the actuator. Actuator 106b also comprises second opening 364, which may be aligned with first opening 362 to engage release actuator 112, as shown. As seen in the cross-sectional view of FIG. 26C, wrap portion 360, and especially the curved portion 361 of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening. In this manner, release actuator 112 may be interference or friction fit through first opening 362 and second opening 364. Retraction of the release actuator proximal of the first and second openings may actuate the releasable attachment mechanism to resiliently or dynami-

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cally unwrap portion 360 and release actuator 106b from post 32. Wrap and/or curved portion 360/361 of actuator 106b illustratively is disposed at a distal end of the actuator.

As will be apparent to those of skill in the art, the releasable attachment mechanism of FIG. 26 may also be utilized to attach an actuator 106a to a braided anchor 30. More generally, wrap portion 360 provides an illustrative first shape on an anchor actuation element 106 that is adapted to mate with a second shape on a post or anchor actuator attachment element (such as element 264 in FIG. 26, or a wire of the braid of anchor 30) to substantially prevent relative distal or proximal movement between the anchor actuation element and the anchor. The apparatus further comprises a release actuator adapted to actuate the releasable attachment mechanism. The release actuator is adapted to be moved to permit relative movement between the first shape and the second shape. This relative movement may change the first shape and/or the second shape to a third shape that permits relative distal or proximal movement between the anchor actuation element and the anchor or post. Furthermore, this relative movement may separate the anchor actuation element from the anchor or actuator attachment element.

FIG. 27 illustrates a variation of the anchor lock element of FIG. 26. In FIG. 27, anchor lock element 34 comprises lock alignment feature 370. Feature 370 comprises engagement portion 372, illustratively a loop, that is adapted to engage post 32 before engagement of anchor lock element 34 (i.e., before engagement of tab 342 of the anchor lock element) with post lock element 260. Feature 370 ensures alignment of the post and buckle prior to locking. Furthermore, feature 370 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole.

Referring now to FIG. 28, actuation of the apparatus of FIG. 27 is described. As seen in FIG. 28A, anchor lock element 34 is advanced distally relative to post 32, for example, by applying a distally-directed force to the anchor via anchor actuator 106a to move the proximal portion of the anchor distally while maintaining the position of post 32 via actuator 106b. Alternatively or additionally, a proximally-directed force may be applied to post 32 via actuator 106b while maintaining the position of the proximal end of the anchor to move the distal portion of the anchor proximally. Lock alignment feature 370 engages the proximal end of the post prior to interlocking of tab 342 of anchor lock element 34 with post lock element 260, thereby ensuring proper alignment. Continued retraction of post 32 relative to buckle 34 locks the post into the buckle, as shown in FIG. 28B. This also expands apparatus 10 to the fully deployed configuration of, e.g., FIGS. 1B and 2C. Next, release actuator 112 is retracted proximally relative to actuator 106b, which causes wrap portion 360 of the actuator to resiliently or dynamically swing outwards, thereby bringing first opening 362 and second opening 364 out of alignment. Proximal retraction of actuator 106b relative to post 32 removes wrap portion 360 from actuator attachment element 264 of post 32.

FIG. 29 shows a variation of the apparatus of FIGS. 27 and 28. In FIG. 29, anchor lock element 34 comprises locking hoop 380, while post lock element 260 comprises a wrapped or curved proximal end of post 32. The curved proximal end also forms actuator attachment element 264. Wrap portion 360 of actuator 106b is wrapped about the curved end of post 32. Release actuator 112, passing through first opening 362 and second opening 364 of actuator 106b, releasably secures this attachment. The release actuator

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further comprises kink 390 that facilitates passage of the actuator through release actuator attachment elements 392 of post 32, illustratively eyelets. When disposed through elements 392, release actuator 112 further acts as a lock prevention mechanism that precludes locking of the curved proximal end of post 32 with hoop 380 of anchor lock element 34.

In use, the proximal end of post 32 may be retracted through hoop 380 of anchor lock element 34. Release actuator 112 then may be retracted relative to anchor actuator 106b and post 32, such that the release actuator is disposed proximal of attachment elements 392 of the post. Next, post 32 may be allowed to distally advance until its curved proximal end catches and locks against hoop 380 of element 34. Continued retraction of release actuator 112 relative to actuator 106b facilitates separation of the actuator from the post, as described previously.

Referring now to FIG. 30, an embodiment of post 32 is described that is configured to lock against the braid of anchor 30, as opposed to a separate anchor lock element 34. Post lock element 260 illustratively comprises bent tab 400 that catches against the anchor braid to lock the anchor in a deployed configuration.

FIG. 31 illustrate locking and unlocking of a variation of anchor lock element 34. Anchor lock element 34 of FIG. 31 is similar to the buckle variation of element 34 described previously with respect to FIGS. 25 and 26. However, the variation of FIG. 31 is fabricated from a strip of material that is bent to form a wrapped or curved portion. FIG. 31A illustrates the apparatus prior to locking, FIG. 31B illustrates the locked configuration, and FIG. 31C illustrates unlocking through application of a proximally-directed unlocking force to unlock actuator 350.

FIG. 32 show yet another embodiment of a releasable actuation mechanism. Anchor lock element 34 comprises lock alignment mechanism 410 disposed proximal of locking tab 412. As shown, lock alignment mechanism 410 engages the distal end of post 32 to align the post and the anchor lock element prior to locking of post lock element 260 with tab 412 of anchor lock element 34. Lock alignment mechanism 410 adds additional strength to anchor lock element 34 and opposes inwardly-directed forces applied to element 34 when valve 20 of apparatus 10 closes during diastole. Advantageously, the inwardly-directed forces act to maintain apparatus 10 in the locked configuration. Mechanism 410 optionally may be formed from a cut tube.

FIG. 33 illustrate a variation of anchor lock element 34 that may be formed from a cut tube. As seen in FIGS. 33A and 33B, element 34 comprises tabs 420 for engaging the curved proximal end of post 32 that forms post locking element 260. In order to lock the post to element 34, the curved distal end of the post is retracted proximally of tabs 420 by the action of proximal tension on post 32 by actuator 106b while element 34 is held stationary, as described above. As it enters anchor lock element 34, the curved end of the post is cammed inward by the engagement of the distal edge of element 34 with the outer surface of the curved end. Once proximal of tabs 420, the curved end of the post moves outward, thereby locking the apparatus and preventing subsequent distal movement of post 32 with respect to element 34. To unlock the apparatus, the curved portion of the post is drawn further proximally by actuator 106b until the tip of the curved portion moves into an opening 422 formed in element 34. As seen in FIGS. 33C and 33D, resilient distal advancement of the post relative to element 34, e.g., via resilient expansion of the braid of anchor 30, deforms and straightens the curved proximal end of post 32 through a

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camming engagement of the underside of the curved portion of the post with the inner surface of opening 422, thereby allowing actuator 106b to slide off of post 32, unlocking apparatus 10. The curved portion of post 32 optionally may be formed from a shape memory material, such that the post resumes its curved profile for subsequent relocking after unlocking.

FIG. 34 illustrate a variation of post 32 and anchor lock element 32. Anchor lock element 34 illustratively comprises a curved portion 35 that engages and enters the slot of post lock element 260 to lock the anchor as post 32 is drawn proximally into element 34 by actuator 106b. After locking, continued proximal retraction of post 32 by actuator 106b engages the distal end of the curved portion of element 34 with a camming surface 430 of post 32. Resilient distal advancement of post 32 (such as by the resilient contraction and elongation of the anchor to its at-rest configuration) then deforms and straightens the wrapped end of element 34, thereby permitting anchor lock element 34 to separate from post 32, unlocking the apparatus.

FIGS. 35 and 36 illustrate additional buckle variations of anchor lock element 34. Proximal movement of post 32 into anchor lock element 34 (by, e.g., actuator 106b) engages a bottom surface 702 of a curved portion 700 of element 34 with the proximal end of post 32. Further proximal movement of post 32 with respect to element 34 cams curved portion 700 forward until the curved end 704 of curved portion 700 meets and resiliently moves into opening 260 in post 32, locking the apparatus. The variation of FIG. 36 illustrates attachment to the braid of anchor 30 via sutures or the like passed through openings 340 in element 34. The lock is unlockable via unlock actuator 350.

Referring now to FIG. 37, an embodiment of a post 32 and anchor lock element 34 with a ratcheting lock is described. Post 32 comprises previously described actuator attachment element 250 that is releasably secured to post attachment element 302 of actuator 106b. (Other releasable attachment mechanisms may alternatively be used.) Post 32 also comprises braid attachment element 430 and valve attachment structure 432. In the variation of FIG. 37, valve attachment structure 432 comprises tab 433 that extends from post 32, as well as a plurality of holes 434 through post 32 and a plurality of holes 435 through tab 433. Replacement valve 20 may be attached to post 32 by sewing the valve to the valve attachment structure through holes 434 and/or 435.

Post 32 further comprises ratcheting locking element 440 having a plurality of inclined planes with camming surfaces 442 and friction surfaces 443. The inclined planes are disposed along either side of tab 433 for ratcheting and locking against ratcheting anchor lock element 34. Anchor lock element 34 comprises ratchet teeth 450 on either side of the valve attachment elements that cam against surface 442 and lock against friction surfaces 443 of element 440 of post 32, as post 32 is proximally retracted through element 34. Advantageously, providing multiple rows of inclined plane ratchets along post 32 facilitates interlocking of the post and the element at multiple discrete locations.

Element 34 comprises proximal and distal slots 452 that receive post 32, as well as central longitudinal slot 453 that facilitate passage of tab 433 (and thereby valve 20) there-through. Actuator 106b may be disposed through slots 452 prior to approximation and locking of the post to anchor lock element 34 in order to facilitate alignment of the post and the anchor lock element. Element 34 may be ratcheted to any position along ratchet lock element 440 to achieve any desired locking configuration and degree of expansion of apparatus 10. Valve attachment structure 432, and thereby

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replacement valve 20, may be positioned proximal of the ratchet lock post-deployment or in line with the ratchet lock (i.e., neither proximal nor distal to the ratchet lock). Element 34 further comprises unlock actuator attachment(s) 454 for coupling the element to an unlock actuator, e.g., previously described unlock actuator 350, to unlock element 34 by applying a proximally-directed unlocking force that displaces ratchet teeth 450 from friction surfaces 443.

FIG. 38 illustrate variations of the apparatus of FIG. 37. Ratchet lock elements 440 of posts 32 in FIG. 38 comprise a plurality of ratchet slots 444 in which ratchet tooth 450 of anchor lock element 34 may be locked. Ratchet tooth 450 comprises proximal friction surface 456 and distal camming surface 457 to facilitate proximal retraction of a post 32 through slot 452 for ratcheting of camming surface 457 through ratchet slots 444, but to preclude distal advancement of the post once ratchet tooth 450 is engaged within ratchet slots 444 by locking a ratchet slot against friction surface 456. As with the variation of FIG. 37, anchor lock element 34 is unlockable and comprises unlock actuator attachment 454. In contrast to the variation of FIG. 37, the ratchet lock is disposed proximally of valve attachment structure 432, and thereby proximally of replacement valve 20. In FIG. 38A, valve attachment structure 432 comprises slot 436 instead of tab 433.

FIG. 39 illustrate another variation of the ratchet lock of FIG. 37. In FIG. 39, ratchet lock elements 440 of post 32 extend along only one edge of the post. Thus, anchor lock element 34 comprises unitary ratchet tooth 450 for camming against surfaces 442 and locking against friction surfaces 443 of elements 440 of post 32, as post 32 is proximally retracted through element 34.

The apparatus of FIG. 39 also comprises unlock or adjustment actuator 500 that is releasably attached to anchor lock element 34 along unlock actuator attachment 454. Actuator 500 comprises two independently or concurrently actuable elements: adjustment element 510 and release element 520. Adjustment element 510 comprises elongated member 512 having protrusion 514 with lumen 515, as well as distal extension 516 with notch 518 having optional camming surface 519. Release element 520 comprises elongated member 521, which may, for example, comprise a mandrel, that is configured for passage through lumen 515 of protrusion 514 of adjustment element 510. Elongated members 512 and 521 of actuator 500 preferably extend through delivery system 100 to the exterior of the patient for independent or concurrent advancement and/or retraction by a medical practitioner.

As seen in FIG. 39A, notch 518 of adjustment element 510 of actuator 500 may be positioned within unlock actuator attachment 454 of anchor lock element 34 during deployment of apparatus 10. As seen in FIG. 39B, anchor lock element 34 is locked within ratcheting lock elements 440 of post 32 by proximally retracting actuator 106b relative to anchor lock element 34. Release element 520 then may be advanced relative to adjustment element 510 to position elongated member 521 within unlock actuator attachment 454 adjacent distal extension 516 of adjustment element 510. This serves to friction lock or interference fit actuator 500 within attachment 454 along notch 518 of adjustment element 510. Thus, concurrent advancement and/or retraction of the adjustment and release elements of actuator 500 by a medical practitioner causes anchor lock element 34 to move in unison with actuator 500. As will be apparent, actuator 500 alternatively may be friction locked with anchor lock element 34 prior to full deployment of apparatus

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10. Furthermore, actuator(s) 500 may assist, or be used in place of, actuators 106a to deploy apparatus 10.

As seen in FIG. 39C, the lock formed between anchor lock element 34 and post 32 may be unlocked or adjusted, as desired, by applying a lateral unlocking force to ratchet tooth 450 via actuator 500 that pulls the ratchet tooth away from a friction surface 443 of ratcheting lock elements 440. Actuator 500 then may be distally advanced or, as seen in FIG. 39D, proximally retracted relative to ratcheting lock elements 440 and post 32 to further expand or partially collapse anchor 30, respectively (further expansion alternatively may be achieved by further ratcheting ratchet tooth 450 along camming surface 442 of ratcheting lock elements 440, e.g., by further proximally retracting actuator 106b, which is not shown in FIGS. 39C-39F for the sake of clarity). Anchor actuation elements 106 may assist such controlled expansion or collapse anchor 30.

When (re-)positioned at a desired location and/or when a desired degree of locking has been achieved, the lateral unlocking force may be removed from ratchet tooth 450 to again lock anchor lock element 34 to post 32 along ratcheting lock elements 440, as in FIG. 39E. To complete deployment of apparatus 10, adjustment actuator 500 and actuator 106b, as well as actuator 106a (not shown), may be separated from the apparatus. In FIG. 39F, release element 520 of actuator 500 is proximally retracted relative to adjustment element 510, thereby removing elongated member 521 of release element 520 from unlock actuator attachment 454 of anchor lock element 34. This removes the interference fit between notch 518 and attachment 454. Proximal retraction of actuator 500 relative to anchor lock element 34 detaches adjustment element 510 of actuator 500 from attachment 454 of anchor lock element 34, as in FIG. 39G. Optional camming surface 519 along notch 518 may facilitate such detachment. In FIG. 39H, actuator 106b is detached from post 32 by retracting release actuator 112 relative to the actuator, as described previously.

Referring now to FIG. 40, another variation of an adjustable ratcheting lock element is described. As seen in FIG. 40A, post 32 comprises tube 470 having lumen 471 and ratcheting lock element 472, illustratively a plurality of slots that communicate with lumen 471. Post 32 also comprises valve support structure or attachment element 474 and braid attachment element 476.

Anchor lock element 34, which may be fabricated from a cut tube, comprises a substantially cylindrical structure having braid attachment element 480, lumen 482 and tabs 484. As seen in the top view of FIG. 40B, tabs 484 of anchor lock element 34 are configured for locking within the slots of ratcheting lock element 472 of post 32. As seen in the top view of FIG. 40C, adjustment actuator 490, illustratively mandrel M having tapered distal end 494 that acts as a camming surface, may be advanced through lumen 481 of anchor lock element 34 and lumen 471 of tube 470 of post 32, to displace tabs 484 from the locking slots of post 32, thereby unlocking the post from the anchor lock element. This facilitates, for example, readjustment of a degree of locking/expansion of apparatus 10, repositioning of apparatus 10, retrieval of apparatus 10, etc.

FIG. 41 illustrate a variation of anchor lock element 34 wherein tabs 484 are positioned along a different axis. This may provide a more secure lock between post 32 and anchor lock element 34. FIG. 42 illustrate a variation of post 32 configured for use with the variation of anchor lock element 34. In FIG. 32, post 32 comprises groove 478 that connects the slots of ratcheting lock element 472. Groove 478 does not communicate with lumen 471 of tube 470 of post 32.

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Rather, the groove may act as a lock alignment mechanism that guides tabs 484 of anchor lock element 34 along post 32 and ratcheting lock element 472, as seen in the top view of FIG. 42B.

Referring now to FIG. 43, a method of actuating the variation of FIG. 41 is described. As seen in FIG. 43A, adjustment actuator 490 is initially disposed through lumen 482 of anchor lock element 34 and within lumen 471 of post 32. Post 32 then may be proximally retracted relative to anchor lock element 34, e.g., via actuator 106b (not shown). In FIG. 43B, actuator 490 serves as a lock prevention mechanism that precludes locking of tabs 484 within ratcheting lock element 472. In FIG. 43C, actuator 490 is retracted relative to post 32 and anchor lock element 34, which opens up lumen 471 of tube 470 and allows tabs 484 to pass through the slots of ratcheting lock element 472, thereby locking the post to the anchor lock element. In FIG. 43D, actuator 490 is re-advanced within lumen 471, such that tapered distal end 494 of mandrel M serves as a camming surface that urges tabs 484 out of lumen 471 as the actuator is advanced. This unlocks the post from the anchor lock element to facilitate adjustment, repositioning or retrieval of apparatus 10. In FIG. 43E, a degree of locking/expansion of the apparatus is adjusted by repositioning anchor lock element 34 relative to post 32, and thereby tabs 484 relative to ratcheting lock element 472. When properly adjusted, actuator 490 may be removed from lumen 471 of tube 470 of post 32, as in FIG. 43F. Tabs 484 resiliently return to the locked configuration within the slots of ratcheting lock element 472.

Referring now to FIG. 44, an embodiment of anchor/actuator 106a is described. Actuator 106a comprises elongated member 600 having proximal extension 602 that may be attached, for example, to previously described multi-lumen shaft or catheter 108 of delivery system/deployment tool 100 (see FIG. 1), e.g., via epoxy, UV curing, etc. Lumen 601 extends through elongated member 600 from proximal extension 602 to releasable attachment mechanism 604. Releasable attachment mechanism 604 releasably attached actuator 106a to the braid of anchor 30. The mechanism comprises release actuator 112 and illustratively is similar to the previously described releasable attachment mechanism of FIGS. 26-28. Release actuator 112, illustratively a mandrel, passes through a lumen Lu of multi-lumen shaft 108 and then through lumen 601 of actuator 106a to mechanism 604.

Actuator 106a further comprises shaping features 606 that affect a shape of the anchor actuator when an anchor actuation force is applied to anchor 30. These features may comprise, for example, reduced diameter portions of the actuator, reduced wall thickness portions of the actuator and/or slits formed in the anchor actuator. Application of an anchor actuation force may, for example, provide actuator 106a with the profile seen in FIG. 44A. This profile may facilitate expansion of anchor 30/apparatus 10. As will be apparent, shaping features may be provided with any anchor actuation elements 106, including any of the previously described variations of actuators 106b.

As seen in FIG. 45, releasable attachment mechanism 604 comprises wrap portion 610 that may, for example, pass through the braid of anchor 30 and wrap around the proximal end of the anchor. Wrap portion 610 may comprise a shape memory material, such as Nitinol, or a deformable material, e.g., a resiliently deformable material. The wrap portion comprises first opening 612 for engaging release actuator 112. The walls of lumen 601 of elongated member 600 may act as a linear bearing and/or motion guide during advance-

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ment and retraction of the release actuator relative to the actuator. Actuator **106a** also comprises second opening **614**, which may be aligned with first opening **612** to engage release actuator **112**, as shown. Wrap portion **610**, and especially curved portion **611** of the wrap portion, acts as a spring element that urges the first opening out of alignment with the second opening to engage and hold release actuator **112** in place.

As seen in FIG. **45C**, when the release actuator is retracted proximally relative to the actuator, wrap portion **610** resiliently or dynamically swings outwards. Thereafter, proximal retraction of anchor actuator **106a** relative to anchor **30** detaches wrap portion **610**, and thereby actuator **106a**, from the anchor. Surface **616** of wrap portion **610** may act as a camming surface as the inner surface of wrap portion **610** slides along the anchor braid **30** to facilitate such detachment.

In this manner, release actuator **112** may be interference or friction fit through first opening **612** and second opening **614**. Retraction of the release actuator proximal of the first and second openings actuates releasable attachment mechanism **604** to resiliently or dynamically unwrap portion **610** and release actuator **106a** from anchor **30**. Wrap portion **610** of actuator **106a** illustratively is disposed at a distal end of the actuator.

With reference to FIG. **46**, a variation of releasable attachment mechanism **604** is described. In FIG. **46**, wrap portion **610** illustratively comprises tabs **618** that act as an alignment mechanism for aligning the wrap portion of mechanism **604** with elongated member **600**. This may facilitate advancement of release actuator **112** through mechanism **604**. FIG. **47** illustrate a variation of tabs **618** wherein the tabs are rounded. This may reduce friction, provide an atraumatic surface, etc. Additional shapes for tabs **618** will be apparent. Alternatively, tabs **618** may act as spring elements which are loaded when element **630** is seated, as shown in FIG. **47B**. In this configuration tabs **618** apply a force directed towards element **630** such that **630** will be ejected when element **112** is retracted. In this way tabs **618** apply a restraining force on element **112** which reduces the risk of an early release.

FIG. **48** illustrate a variation of wrap portion **610** that comprises a substantially straight distal region in an at-rest configuration, as seen in FIG. **48C**. It is expected that providing a substantially straight distal region along wrap portion **610** may facilitate detachment of actuator **106a** from anchor **30**, i.e., may reduce a risk of snagging the wrap portion along the braid of the anchor. The wrap portion may be resiliently deformed for passage, of release actuator **112** through first opening **612**, as in FIGS. **48A** and **48B**.

Referring now to FIG. **49**, variations of release actuator **112** for use with releasable attachment mechanism **604** are described. In FIG. **49A**, the release actuator comprises a simple mandrel. In FIGS. **49B** and **49C**, the release actuator comprises protrusion **620** having friction surface **621**. In FIG. **49D**, actuator **112** comprises coil **622**. In FIGS. **49E-49H**, the actuator comprises kink **624**, which may act as a camming surface, as shown. The kink may also provide tactile feedback to a medical practitioner. In FIGS. **49I** and **49J**, the release actuator comprises ball or knob **626** disposed proximal of the actuator's distal end. In FIGS. **49K** and **49L**, ball **626** is disposed at the distal end of actuator **112**. The ball may act as a camming surface. In FIG. **49M**, actuator **112** comprises protrusion **628** having proximal camming surface **629**. In FIG. **49N**, the actuator comprises oblong protrusion **430** having friction surface **431**. Additional variations of actuator **112** will be apparent.

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Referring now to FIG. **50**, an embodiment of delivery system/deployment tool **100** is described. FIG. **50A** provides a detail view of multi-lumen catheter **108** and sheath **110**. As discussed previously catheter **108** comprises central lumen **109** and a plurality of circumferentially-disposed lumens **Lu**.

As seen in FIG. **50B**, actuator **106a** is coupled to catheter **108** via proximal extension **602**, such that lumen **601** is coaxially disposed within a lumen **Lu** of the catheter. Release actuator **112** extends through lumens **Lu** and **601**. Actuator **106a** is distally attached to the braid of anchor **30** along releasable attachment mechanism **604**. For the sake of clarity, a single actuator **106a** is shown in FIG. **50B**, but multiple such actuators preferably are provided, as in FIG. **51** described hereinafter.

FIG. **50B** also illustrates actuator **106b**. The actuator extends through a lumen **Lu** of catheter **108** and through anchor lock element **34** to post **32** (not shown). Unlock actuator **350** is also provided and extends through a lumen **Lu** to unlock actuator attachment **344** of anchor lock element **34**. Anchor lock element **34** illustratively comprises the variation described previously with respect to FIG. **31**. The element is attached to the braid of anchor **30** along anchor attachment elements **340**. As with actuator **106a**, a single anchor lock element **34** and actuator **106b** are shown in FIG. **50B**. This is only for the sake of clarity, and multiple such actuators may be provided, e.g., three actuators.

Referring now to FIG. **51**, delivery system/deployment tool **100** is shown with a plurality of actuators **106a** and actuators **106b** for releasable attachment to anchor **30** of apparatus **10**. In FIG. **51A**, anchor actuation elements **106a** are coupled to the anchor. In FIG. **51B**, the elements are decoupled from the anchor.

With reference now to FIG. **52**, a variation of the delivery system/deployment tool of FIGS. **50** and **51** is described comprising a plurality of arms or actuators that extend from a unitary structure. Unitary structure **650**, which may extend from a distal region of multi-lumen shaft **108**, is preferably fabricated from a laser-cut tube. Structure **650** comprises a plurality of circumferentially disposed arms **652** that serve as actuators. Expansile elements **654** may be disposed between arms **652** and facilitate constraint of the arms radially outward or inward with respect to other arms as the anchor reshapes. FIG. **52A** shows the arms in a radially collapsed configuration, and FIG. **52B** shows the arms in a radially expanded configuration. Wrap portions **655** are adapted to wrap around the proximal portion of an anchor braid. Openings **656** and **657** are formed in wrap portions **655** to engage a release actuator, as described in embodiments above.

Referring now to FIG. **53**, various ways to connect elements to the braid of anchor **30** of replacement valve apparatus **10** are described. In FIG. **53A**, a post **32** having a single braid attachment hole **660** is attached to anchor **30** along three separate intersections of the braid via suture **S**. FIG. **53B** provides a detail view of one exemplary technique for routing the suture between hole **660** and anchor **30**. FIG. **53C** illustrates a variation of the attachment, wherein post **32** comprises multiple braid attachment holes **660**. As will be apparent, elements other than posts **32** may be attached to anchor **30** in the manner described, for example, anchor lock elements **34** may be attached in a similar manner.

While preferred embodiments of the present invention are shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will occur to those skilled in the art without departing from the invention. For example, while the invention was

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described in connection with the replacement of a natural valve, the invention may also be used to replace an earlier-implanted prosthetic valve. Also, while the preceding discussion described the use of the invention to deliver and deploy replacement heart valves, it should be understood that the invention is not limited to that particular use. Other aspects of the invention include methods and apparatuses for endovascularly, percutaneously and/or endoscopically delivering and deploying expandable devices in a patient and optionally detaching a deployment tool from the device.

It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

The invention claimed is:

1. A system, comprising:

an outer delivery sheath;

a replacement heart valve comprising an expandable anchor member configured to be implantable within a patient; and

a deployment tool extending through the outer delivery sheath to the replacement heart valve, the deployment tool comprising an attachment mechanism configured to engage the expandable anchor member and a release actuator configured to releasably secure the expandable anchor member to the attachment mechanism;

wherein the release actuator is positioned generally parallel to the attachment mechanism and translation of the release actuator relative to the attachment mechanism permits the expandable anchor member to disengage from the attachment mechanism;

wherein the attachment mechanism encircles at least a portion of the expandable anchor member when the expandable anchor member is releasably secured to the attachment mechanism.

2. The system of claim 1, wherein at least a portion of the expandable anchor member extends through the attachment mechanism when the expandable anchor member is releasably secured to the attachment mechanism.

3. The system of claim 1, wherein axial translation of the release actuator relative to the attachment mechanism permits the expandable anchor member to disengage from the attachment mechanism.

4. The system of claim 3, wherein proximal axial translation of the release actuator relative to the attachment mechanism permits the expandable anchor member to disengage from the attachment mechanism.

5. The system of claim 1, wherein the deployment tool includes an elongate shaft and the attachment mechanism is attached to a distal end of the elongate shaft.

6. The system of claim 1, wherein an attachment mechanism is configured to engage a proximal end of the expandable anchor member.

7. The system of claim 1, wherein axial translation of the deployment tool relative to the outer delivery sheath shifts the expandable anchor member between a collapsed configuration and an expanded configuration.

8. The system of claim 1, further comprising a control handle coupled to the deployment tool and the outer delivery sheath, wherein the control handle is configured to translate the deployment tool relative to the outer delivery sheath.

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9. The system of claim 8, wherein the control handle is further configured to translate the release actuator relative to the attachment mechanism.

10. The system of claim 1, wherein the deployment tool includes three attachment mechanisms and three corresponding release actuators positioned generally parallel to their respective attachment mechanism.

11. A system, comprising:

an outer delivery sheath;

a replacement heart valve comprising an expandable anchor member configured to be implantable within a patient; and

a deployment tool extending through the outer delivery sheath to the replacement heart valve, the deployment tool comprising an attachment mechanism configured to engage the expandable anchor member and a release actuator configured to releasably secure the expandable anchor member to the attachment mechanism;

wherein the release actuator is positioned generally parallel to the attachment mechanism and translation of the release actuator relative to the expandable anchor member permits the expandable anchor member to disengage from the attachment mechanism;

wherein the attachment mechanism forms a closed loop around at least a portion of the expandable anchor member when the expandable anchor member is releasably secured to the attachment mechanism.

12. The system of claim 11, wherein at least a portion of the expandable anchor member extends through the attachment mechanism when the expandable anchor member is releasably secured to the attachment mechanism.

13. The system of claim 11, wherein axial translation of the release actuator relative to the expandable anchor member permits the expandable anchor member to disengage from the attachment mechanism.

14. The system of claim 13, wherein proximal axial translation of the release actuator relative to the expandable anchor member permits the expandable anchor member to disengage from the attachment mechanism.

15. The system of claim 11, wherein the deployment tool includes an elongate shaft and the attachment mechanism is attached to a distal end of the elongate shaft.

16. The system of claim 11, wherein an attachment mechanism is configured to engage a proximal end of the expandable anchor member.

17. The system of claim 11, wherein axial translation of the deployment tool relative to the outer delivery sheath shifts the expandable anchor member between a collapsed configuration and an expanded configuration.

18. The system of claim 11, further comprising a control handle coupled to the deployment tool and the outer delivery sheath, wherein the control handle is configured to translate the deployment tool relative to the outer delivery sheath.

19. The system of claim 18, wherein the control handle is further configured to translate the release actuator relative to the expandable anchor member.

20. The system of claim 11, wherein the deployment tool includes three attachment mechanisms and three corresponding release actuators positioned generally parallel to their respective attachment mechanism.

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